ORAL ARGUMENT NOT YET SCHEDULED

NO. 18-5004

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Plaintiffs-Appellants,

v.

ALEX M. AZAR II, in his official capacity, *et al.*,
Defendants-Appellees.

On Appeal from a Final Judgment of the
United States District Court for the District of Columbia,
(Honorable Rudolph Contreras)

BRIEF OF 35 STATE AND REGIONAL HOSPITAL ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

A. Parties and *amici*

All parties, intervenors, and amici are listed in the Certificate as to Parties, Rulings Under Review, and Related Cases filed by Plaintiffs-Appellants in this Court on February 12, 2018,

B. Rulings under review

References to the rulings at issue appear in the Certificate as to Parties, Rulings Under Review, and Related Cases filed by Plaintiffs-Appellants in this Court on February 12, 2018,

C. Related cases

Amici are not aware of any cases related to this appeal.

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CORPORATE DISCLOSURE STATEMENT

Amici curiae are non-profit organizations and one Limited Liability Company (Suburban Hospital Alliance of New York State). They have no parent corporations and do not issue stock.

STATUTES AND REGULATIONS

The pertinent statues and regulations are:

- 42 U.S.C § 256b
- 42 C.F.R. § 412.92
- 42 U.S.C. § 1396r-8
- 82 Fed. Reg. 33,558, 33,711 (July 20, 2017)
- 82 Fed. Reg. 52,356, 52,362, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017)

These statutes and regulations are reprinted in the addendum to this brief.

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are 35 state and regional hospital associations that represent thousands of hospitals and health systems.[2] *Amici* and their members are fully committed to improving the health of the communities they serve through the delivery of high quality, efficient, and accessible health care. The 340B Drug Pricing Program is a critical tool in helping to achieve this goal.

Many of the hospitals and health systems that *amici* represent will be severely harmed by the Centers for Medicare and Medicaid Services' ("CMS") revision to the reimbursement rates for drugs purchased through the 340B Program. The reduction in the reimbursement rate will cause these safety-net hospitals to lose hundreds of millions of dollars in funding. As a result, scores of low-income, uninsured, underinsured, and homeless patients will be unable to receive the same level of care. *Amici* therefore have a strong interest in ensuring that their member 340B hospitals do not face an unprecedented, precipitous, and—most significantly—unlawful diminution of this vital funding. They respectfully

[1] In accordance with Federal Rule of Appellate Procedure 29(a)(4)(E), *amici* certify that (1) this brief was authored entirely by counsel for *amici curiae* and not by counsel for any party, in whole or part; (2) no party or counsel for any party contributed money to fund preparing or submitting this brief; and (3) apart from *amici curiae* and their counsel, no other person contributed money to fund preparing or submitting this brief.

[2] The individual associations are described in Appendix A.

submit this brief to provide the Court with information directly relevant to its consideration of this appeal.

INTRODUCTION

Amici are 35 state and regional hospital associations. Their member hospitals and health systems employ thousands of medical professionals and treat millions of America's poorest patients. The health care services that *amici*'s member institutions provide to our nation's most vulnerable communities are often uncompensated or deeply discounted. *Amici*'s member institutions therefore rely on the 340B Drug Pricing Program ("340B"), which saves them millions of dollars each year on the purchase of outpatient drugs. As it is, these member hospitals stretch their own resources to provide care to our neediest citizens. And as Congress intended, the savings from 340B enable these members to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Now, however, CMS has issued a final rule that will stretch *amici*'s members beyond the breaking point.[4]

This Court has long recognized 340B's purpose. In *University Medical Center of Southern Nevada v. Shalala*, it observed that Congress established 340B because it was "concerned that many federally funded hospital facilities serving low-income patients were incurring high prices for drugs."[5] But CMS's massive

[3] H.R. Rep. No. 102-384(II), at 12 (1992).

[4] *See* 82 Fed. Reg. 52,356, 52,493–52,511, 52,622–52,625 (Nov. 13, 2017).

[5] *See Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999)*; see Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human*

cuts to 340B are irreconcilable with Congress's goal of allowing hospitals to offset the high cost of prescription drugs so that they can direct their limited resources towards patient care and services. These cuts constitute a "severe restructuring of the statutory scheme" that will have profound effects on patients and health care providers across the country.[6] Drug costs will increase and safety-net providers will face hard choices about eliminating or dramatically curtailing crucial programs that treat a wide range of medical conditions—from cancer to mental health disorders to diabetes to opioid addiction to HIV/AIDS.

The numbers alone are staggering. Initially, CMS predicted that the new rule would cost safety-net providers "as much as $900 million" in reimbursements.[7] But CMS undershot the financial cost of their proposal by nearly 80 percent. By the time the agency issued the final rule, the estimated cost had ballooned to roughly *$1.6 billion*.[8]

Servs., 138 F. Supp. 3d 31, 34, 52 (D.D.C. 2015) (the "*general* stated purpose" of 340B at the time of its "initial passage in 1992" was "'to stretch scarce Federal resources as far as possible'" to ensure broad "access to drugs at a reduced cost for certain entities and in certain circumstances" (quoting H.R. Rep. No. 102-384(II), at 12) (emphasis omitted)).

[6] *Amgen, Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004).

[7] 82 Fed. Reg. 33,558, 33,711 (July 20, 2017).

[8] 82 Fed. Reg. 52,356, 52,623 (Nov. 13, 2017).

But those numbers tell only a small part of the story. The real impact of CMS's rule lies beneath those numbers, in the lived experience of vulnerable patients for whom subsidized care and services may no longer be available and the hospitals and clinics that will no longer be able to effectively serve them. *Amici* and their members are acutely aware of these real-world effects because they are on the front lines of providing irreplaceable care to their communities, including those most in need.

Having decided this case on a threshold ground, the district court did not consider these immediate and irreparable consequences and, in fact, denied *amici*'s motion for leave to submit a similar amicus brief.[9] But those consequences not only highlight why, contrary to the district court's conclusion, formalistic presentment and administrative exhaustion rules are dangerously futile; they also demonstrate why this Court should reverse the district court's decision to deny a preliminary injunction and enjoin the Department of Health & Human Services (HHS) rule pending remand. Given their unique position, *amici* respectfully submit this brief to inform the Court about what will happen if CMS is permitted to take a scalpel—or really, an old-fashioned amputation saw—to 340B.

[9] *Am. Hosp. Ass'n v. Hargan*, No. CV 17-2447 (RC), 2017 WL 6734176, at * 7, n. 1 (D.D.C. Dec. 29, 2017).

ARGUMENT

I. CONGRESS CREATED THE 340B PROGRAM TO ENABLE COVERED ENTITIES TO EXPAND HEALTH CARE SERVICES IN COMMUNITIES WITH VULNERABLE PATIENTS.

Medicaid has long been the "Nation's largest single purchaser of prescription drugs."[10] But for decades, "it usually pa[id] the highest prices" for those drugs, while "other large purchasers received discounts from drug manufacturers."[11]

To remedy this imbalance, in 1990 Congress enacted the Medicaid Rebate Program.[12] Under this program, a drug manufacturer could not be covered by Medicaid funds for any of its outpatient drugs unless it first entered into a contract with the Secretary of Health and Human Services (or, in some instances, with a state designee).[13] The contract required the manufacturer to offer states a rebate on their purchases of certain prescription drugs, and the size of the rebate would be

[10] Melvina Ford, Cong. Research Serv., *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS-17 (Mar. 7, 1991); *see also* H.R. Rep. No. 102-384(II), at 9.

[11] Melvina Ford, *supra* note 10 at CRS-15.

[12] *See* 42 U.S.C. § 1396r-8.

[13] *Id.*; *see also* H.R. Rep. No. 102-384(II), at 9.

calculated based on the "best price" the drug manufacturer had given to any purchaser for a particular drug as of September 1, 1990.[14]

Though well-intentioned, the Medicaid Rebate Program was imperfect in practice. Perhaps most problematic, many drug manufacturers simply discontinued the discounts that they had been offering non-state purchasers and raised the "best price" for the most common drugs among Medicaid patients across the board.[15] As a result, the "[p]rices paid for outpatient drugs by . . . Federally-funded clinics and public hospitals" surged.[16] In other words, the Medicaid Rebate Program inflicted collateral damage on hospitals by inflating their costs for outpatient drugs.

Congress moved to repair the damage in 1992 with the 340B Drug Pricing Program. Named for the section of the Public Health Services Act that established the program, the 340B Drug Pricing Program was intended to ensure that the same "Federally-funded clinics and public hospitals" that had been harmed by the Medicaid Rebate Program could acquire outpatient drugs from manufacturers at discounted prices. In essence, 340B requires drug companies to sign contracts with the Secretary of Health and Human Services in which they promise to sell drugs to certain health care providers (known as "covered entities") at or below a

[14] H.R. Rep. No. 102-384(II), at 9; *see Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 114–15 (2011) (explaining the Medicaid Rebate Program).

[15] H.R. Rep. No. 102-384(II) at 9–10.

predetermined ceiling price in exchange for having their drugs covered under Medicaid.[17] Congress did not, however, adjust the reimbursement rates that the covered entities receive from Medicare or Medicaid for the outpatient drugs the entities purchased. Consequently, under 340B, covered entities can use the difference between the discounted price for outpatient drugs and the standard reimbursement to support a range of programs and services that benefit their communities. Put another way, 340B provides covered entities with valuable financial relief that comes at no cost to the government.

To qualify as a "covered entity," a health care provider generally must serve a high volume of the country's most vulnerable patients. Among these qualifying providers are safety-net hospitals.[18] Safety-net hospitals "play a vital role in our health care system, delivering significant care to Medicaid, uninsured, and other vulnerable patients."[19] Such hospitals often provide services that other hospitals do

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[16] *Id.* at 11.

[17] *See* 42 U.S.C. § 256b(a)(1); *see also Astra USA Inc.*, 563 U.S. at 113 ("Section 340B of the Public Health Services Act imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities. Those facilities, here called '340B' or 'covered' entities, include public hospitals and community health centers, many of them providers of safety-net services to the poor." (citation omitted)).

[18] *See* 42 U.S.C. §§ 256b(a)(4)(A)–(L).

[19] Allen Dobson, Joan DaVanzo & Randy Haught, The Commonwealth Fund, *The Financial Impact of the American Health Care Act's Medicaid Provisions on Safety-Net Hospitals* 2 (June 2017),

not, including trauma care, burn care, neonatal intensive care, and inpatient behavioral health.[20] Safety-net hospitals treated more than 6.2 million patients, provided 33 percent of all inpatient days of care for Medicaid patients, and provided nearly 30 percent of all hospital uncompensated care in 2015.[21] Other covered entities include community health centers (which serve as the primary health care facility for more than 27 million people in 9,800 rural and urban communities across the countries),[22] Ryan White clinics (which provide primary medical care and support to uninsured or underinsured individuals living with

http://www.commonwealthfund.org/~/media/files/publications/fund-report/2017/jun/dobson_ahca_impact_safety_net_hosps_v2.pdf.

[20] *Id.*; *see also* America's Essential Hospitals, *About—Establishing the Safety Net Hospital: 1980–2005*, https://essentialhospitals.org/about-americas-essential-hospitals/history-of-public-hospitals-in-the-united-states/establishing-the-safety-net-hospital-1980-2005/ (last visited Feb. 21, 2018).

[21] Allen Dobson, Joan DaVanzo & Randy Haught, *supra* note 19 at 4.

[22] *See* 42 U.S.C. § 256b(a)(4)(A); Nat'l Ass'n of Community Health Centers, *About Our Health Centers*, http://www.nachc.org/about-our-health-centers/ (last visited Feb. 21, 2018).

HIV),[23] Black Lung clinics,[24] Hemophilia Treatment Centers,[25] and family planning clinics.[26]

In 2010, when Congress passed the Patient Protection and Affordable Care Act ("ACA"), it added a number of entities to 340B's definition of "covered entities."[27] It now also includes:[28] freestanding cancer hospitals; critical access hospitals;[29] sole community hospitals;[30] rural referral centers;[31] and certain children's hospitals. Together, these covered entities serve the neediest and most vulnerable members of society—and they do so without regard to whether those patients have the ability to pay for the services they receive.

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[23] *See* 42 U.S.C. § 256b(a)(4)(D); Health Resources & Services Administration, *About the Ryan White HIV/AIDS Program* (Oct. 2016), https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program.

[24] *See* 42 U.S.C. § 256b(a)(4)(F).

[25] *See* 42 U.S.C. § 256b(a)(4)(G).

[26] *See* 42 U.S.C. § 256b(a)(4)(C).

[27] *Pharm. Research & Mfrs. of Am.*, 138 F. Supp. 3d at 35 (explaining that "Congress added a significant number of new categories to the list of covered entities" as part of the ACA).

[28] *See* 42 U.S.C. §§ 256b(a)(4)(M)–(O).

[29] Rural Health Information Hub, *Critical Access Hospitals (CAHs)* (Apr. 8, 2015), https://www.ruralhealthinfo.org/topics/critical-access-hospitals.

[30] 42 C.F.R. § 412.92.

In creating 340B, Congress acknowledged the critical role these entities play in the lives of low-income and rural Americans. It sought to offset the considerable costs these entities necessarily incur by providing health care to the uninsured, underinsured, and those who live far from hospitals and clinics. Congress hoped that "[i]n giving these 'covered entities' access to price reductions" on outpatient drugs, the entities would be able to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[32] Because covered entities would be able to spend less on outpatient drugs—without any concomitant decrease in their Medicaid, health insurance, and federal grant reimbursements—they could use their 340B savings to widen the safety net that they offer to low-income and vulnerable populations.[33]

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[31] Health Resources & Services Administration, *Rural Referral Centers* (Sept. 2017), https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/rural-referral-centers/index.html.

[32] H.R. Rep. No. 102-384(II), at 12.

[33] *See also* Health Resources & Services Administration, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 14 (July 2005), https://www.hrsa.gov/sites/default/files/opa/programrequirements/forms/hemophiliatreatmentcenter340bmanual.pdf ("The purpose of the 340B Program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are

II. THE 340B PROGRAM HAS ALLOWED COVERED ENTITIES TO STRETCH SCARCE FEDERAL RESOURCES AND PROVIDE VITAL SERVICES TO VULNERABLE POPULATIONS.

In the twenty-five years since Congress enacted 340B, safety-net providers like *amici*'s members have successfully implemented Congress's vision: 340B has generated substantial savings for health care providers that serve the country's most vulnerable populations, allowing them to convert these savings into a broader safety net that "reach[es] more eligible patients and provid[es] more comprehensive services."[34]

A. 340B has allowed covered entities to offer a wide range of vital medical services

At a recent congressional hearing, Congressman Frank Pallone declared: "It is beyond question that the resources provided through the 340B Drug Pricing Program directly augment patient care throughout the country."[35] For support, Congressman Pallone could easily turn to powerful evidence in the administrative

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lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts or rebates.").

[34] H.R. Rep. No. 102-384(II), at 12.

[35] *See* Examining How Covered Entities Utilize the 340B Drug Pricing Program Before the House of Representatives Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, 115th Cong., at p. 17 (Oct. 11, 2017), http://docs.house.gov/meetings/IF/IF02/20171011/106498/HHRG-115-IF02-Transcript-20171011.pdf.

record that was submitted by the *amici* hospital associations and other safety-net providers. For example:

- *Amicus* North Carolina Healthcare Association, explained that "North Carolina Hospitals use 340B savings to provide local access to drugs and treatments for cancer patients, clinical pharmacy services, community outreach programs, free vaccinations, transportation to patients for follow-up appointments and many other needed services to their communities as well as partially offsetting uncompensated care and Medicaid losses."[36]

- *Amicus* California Hospital Association similarly explained that "[h]ospitals in California use the 340B savings to provide free care for uninsured patients, free vaccinations and services in mental health clinics, medication management programs and community health programs."[37]

- *Amicus* Louisiana Hospital Association commented that their members participating in the 340B Program had margins of *negative* 19.35 percent, and that the cuts would "make these hospitals' financial situations even more precarious, thus putting at risk the programs that they have developed to expand access to care for their vulnerable patient populations."[38]

- The Safety Net Hospital Alliance of Florida noted in their comments to CMS that the 340B Program "has been critical to ensuring that low-income and other disadvantaged people have access" to vital medical services, including "lifesaving cancer and transplant drugs at no cost[;] . . . clinical pharmacy programs, in which pharmacists interact

[36] North Carolina Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 2 (Sept. 11, 2017).

[37] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 4 (Sept. 11, 2017).

[38] Louisiana Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3 (Sept. 6, 2017).

> with patients at bedside and in the emergency department[;] and "mental health and substance abuse treatment."[39]

These hospital associations are not unique. In one study, 67 percent of the hospitals surveyed reported that their 340B savings have helped them fund patient-assistance programs that they otherwise likely could not afford.[40] The nature of these programs and facilities varies widely, in accordance with the diverse needs of the populations those covered entities serve. Indeed, as Charlie Reuland, the Executive Vice President and Chief Operating Officer of the Johns Hopkins Hospital, told the House Committee on Energy and Commerce, "[t]he great strength of the 340B Program is the discretion it affords eligible hospitals in tailoring the use of program savings to address the unique needs of our communities."[41]

Some covered entities have used their 340B savings to provide low-income patients with comprehensive care networks of social workers, pharmacists, diabetes educators, dieticians, and home health nurses, all of whom provide

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[39] Safety Net Hospital Alliance of Florida, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 6–7 (Sept. 13, 2017).

[40] 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients* 4, 11 (May 2016), https://www.340bhealth.org/files/Savings_Survey_Report.pdf.

[41] *See* Examining How Covered Entities Utilize the 340B Drug Pricing Program, *supra* note 35 at 39.

follow-up care to patients after they leave the hospital.[42] Other entities have chosen to create oncology centers, women's health centers, stroke and spasticity clinics, infusion clinics, and neonatal "programs for expectant mothers" in vulnerable communities in an effort to "increase the likelihood of healthy on-time deliveries" and diminish the probability of NICU stays.[43] Still others have used their 340B savings to offer transportation to appointments to patients who do not own a car or to fund mobile health vans or "mammography coaches," which travel around conducting free or deeply discounted health screenings in low-income communities.[44]

Savings from the 340B Drug Pricing Program also allow health care providers to expand the range of medications and medical devices that are available to low-income patients. In one study, 71 percent of respondents reported that their 340B savings "increase their ability to provide free or discounted drugs to low income patients."[45] Forty-one percent, moreover, said that 340B has an impact

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[42] California Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 3 (Sept. 11, 2017).

[43] Examining How Covered Entities Utilize the 340B Drug Pricing Program *supra* note 35 at 41.

[44] 340B Health, *Faces of 340B: Mark Huffmyer*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/mark-huffmyer/.

[45] *340B Program Helps Hospitals Provide Services to Vulnerable Patients supra* note 40 at 9.

on the range of drugs and devices they are able to provide.[46] For some patients, 340B is the key that has unlocked chemotherapy; IVIg infusions, which can be used to help those with certain immune deficiencies; osteoporosis prophylaxis; treatment for Pompe disease, a disorder caused by the build-up of glycogen in the body; and treatment for rabies.[47]

B. 340B has had a meaningful impact on patients' lives

A hospital's mission is to treat patients. When hospitals thrive, patients will thrive too. As the stories below demonstrate, 340B enables hospitals to achieve their mission.

Jennifer Gallagher is one of many patients for whom the 340B Program has had a tangible, beneficial impact.[48] In 2013, Ms. Gallagher underwent an open heart surgery that requires her to be on a powerful blood thinner for the rest of her life. This expensive medication requires near-constant monitoring, requiring countless trips to and from a health care provider.[49] Fortunately, Ms. Gallagher lives near Parkview Medical Center in Pueblo, Colorado. Thanks in large part to

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[46] *Id.* at 4.

[47] *Id.* at 10.

[48] 340B Health, *Faces of 340B: Jennifer Gallagher*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/jennifer-gallagher/.

[49] *Id.*

the 340B Program, Parkview can offer Ms. Gallagher's blood thinner at a discounted price and to run an outpatient anticoagulation clinic that Ms. Gallagher depends on for care.[50] If not for those services, Ms. Gallagher would have to travel a considerable distance for treatment, making it difficult for her to retain a job. And she would struggle to afford the medication on which her life depends.[51]

Lamar Williams was uninsured when he suffered three heart attacks.[52] After the third attack, Mr. Williams was enrolled in Baptist Medical Center's CareAdvisor Program in Montgomery, Alabama. Through the program, which is funded through the medical center's 340B savings, Mr. Williams receives not only medical care but also bus passes, medications, a nurse case manager, and a social worker—all free of charge.[53] Mr. Williams credits the program with saving his life.[54]

Linda, a patient at St. Joseph's Health—a member of *amici* New Jersey Hospital Association—has likewise directly benefitted from 340B savings in the wake of her recent Hepatitis C diagnosis. With the help of 340B, St. Joseph's has

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[50] *Id.*

[51] *Id.*

[52] 340B Health, *Faces of 340B: Lamar Williams*, http://www.340bhealth.org/340b-resources/why-340b-matters/faces-of-340b/lamar-williams/.

[53] *Id.*

[54] *Id.*

been able to provide Linda a promising new Hepatitis C drug. As a single mother of two also caring for an ailing parent, Linda could not afford the medication—at a cost of more than $1,100 a pill—without significant support from 340B.

Finally, not long ago, one patient at Chicago's Mount Sinai Hospital—a member of *amici* Illinois Health and Hospital Association—was diagnosed with a lethal brain parasite. If not for 340B, the medication therapy needed to eliminate the parasite would have been roughly $20,000—a prohibitive expense. But thanks to Mount Sinai's 340B funds, the hospital was able to offer the medication to the patient at an affordable price. In other words, the 340B Program was a literal life-saver.

Countless other patients could attest to the impact that 340B has had on their lives. Together, these narratives provide overwhelming evidence of the success of Congress's vision in creating that program.

III. THE NEW RULE WOULD SIGNIFICANTLY DIMINISH *AMICI*'S ABILITY TO PROVIDE COMPREHENSIVE SERVICES TO VULNERABLE POPULATIONS.

Twenty-five years after 340B was first introduced, it now faces a dangerous threat in the new rule issued by CMS on November 1, 2017.[55] Under that rule, covered entities are still entitled to purchase outpatient drugs at discounted prices. Now, however, they will receive severely diminished reimbursements for those

[55] 82 Fed. Reg. 52,356 (Nov. 13, 2017).

payments. Before, the covered entities' reimbursements from Medicare were typically the average sales price ("ASP") of a particular drug *plus 6 percent*. Now, the reimbursements will be the ASP *minus 22.5 percent*.[56] This nearly *30 percent reduction* in the reimbursement rate will have devastating consequences for 340B hospitals and the millions of patients they serve.

DataGen, a company that analyzes Medicare payment policy changes for 47 state hospital associations and other clients,[57] conducted a study to estimate the 340B payment reductions on a state-by-state basis. Its study concluded that health care providers in each of the *amici*'s states should expect their reimbursement for drugs acquired under the 340B Program to decrease by the following amounts:[58]

State	**340B Reduction**
Alabama	$39,720,400
Arkansas	$14,507,000
California	$173,965,500

[56] *Id.* at 52,362.

[57] DataGen, *About DataGen*, http://datagen.info/about/ (last visited Feb. 21, 2018).

[58] In the CY2018 Outpatient Prospective Payment System (OPPS) Final Rule Impact file, CMS mistakenly identified several hospitals as Rural Sole Community Hospitals (SCHs). This resulted in the calculation of a lower impact from the 340B reductions for certain states because Rural SCHs are exempted from the new reimbursement cut. CMS corrected this error after *amici* filed its brief in the lower court proceedings. The revised numbers reflect the estimated 340B impact using the corrected CMS data, and demonstrate that certain states will suffer additional harm as a result of the 340B reductions.

Colorado	$35,631,500
Georgia	$80,127,500
Illinois	$72,645,000
Iowa	$19,377,800
Kansas	$22,493,400
Louisiana	$43,278,000
Maine	$15,888,600
Massachusetts	$59,280,300
Michigan	$72,754,500
Minnesota	$36,802,200
Mississippi	$29,517,500
Missouri	$47,998,200
New Jersey	$29,518,800
New Mexico	$12,851,500
New York	$96,000,200
North Carolina	$102,343,300
North Dakota	$14, 969,100
Ohio	$52,668,700
Oregon	$21,341,400
Pennsylvania	$82,017,100
South Dakota	$17,709,000
Tennessee	$62,778,500
Texas	$42,356,500
Vermont	$6,426,700
Washington	$50,320,800
West Virginia	$16,148,500
Wisconsin	$40,668,800

CMS has concededly attempted to offset some of these multi-million-dollar losses with separate budget-neutrality measures. But those budget-neutrality

measures will only *partially* offset the financial damage for certain covered entities. The vast majority of *amici* still expect the damage inflicted by the new rule to be debilitating. The 340B providers in the California Hospital Association, for instance, still stand to lose approximately $85 million, even after the proposed budget-neutrality measures are implemented. The forty-three 340B hospitals that are part of the Georgia Hospital Association anticipate a loss of approximately $57 million in 2018. And the 340B providers in the Tennessee Hospital Association still expect they will have to overcome a difference of at least $45.5 million. In short, to the extent there are hospitals for which the proposed budget neutrality measures will actually obviate the financial blow inflicted by the cuts to the 340B Program, these hospitals are the exception—not the rule.

Even accounting for these offsets, these numbers provide only an aggregate picture. On a granular level, particular covered entities within each state stand to suffer even more. Whereas budget-neutrality measures may help offset the *overall* impact to a state's hospitals or health systems, *individual* 340B-hospitals will be forced to cope with reductions in funding that will sap their ability to maintain their current range of health care services.

Stated differently, increasing the Medicare Part B reimbursement rates for other types of services does not help all hospitals equally. For example, data from the 2016 American Hospital Association Annual Survey suggests that 25.8% of

340B hospitals affected by the new rule *already* had negative operating margins before these cuts took effect.[59] The following are just a few of the many individual hospitals that will suffer under CMS's rule:

Covered Entity	**Projected**
John D. Archbold Memorial Hospital (Thomasville, GA)	$2,300,000
Maimonides Medical Center (Brooklyn, NY)	$4,000,000
Midtown Medical Center (Columbus, GA)	$2,886,200
Oregon Health & Science University (Portland, OR)	$11,000,000
Presence Health System (IL)	$7,709,482
Reading Hospital (West Reading, PA)	$18,276,068
Saint Francis Medical System (Cape Girardeau, MO)	$1,038,000
UC Health (CO)	$17,000,000
University of New Mexico Comprehensive Cancer Center (NM)	$9,600,000

Not surprisingly, most covered entities will be unable to weather these financial losses for long without making painful adjustments to the range of medical services they can provide.[60] Indeed, 40 percent of hospital respondents predicted that losing their 340B savings would force them to close one or more clinics entirely; 37 percent predicted that, without 340B, they would have to close

[59] *See* AHA Data, *Data Collection Methods*, http://www.ahadata.com/data-collection-methods/.

[60] *340B Program Helps Hospitals Provide Services to Vulnerable Patients supra* note 40 at 5 ("340B savings impact the bottom line for our organization . . . The loss of 340B savings would put the hospital in the red. All services would be affected.").

one or more outpatient pharmacies; and 71 percent forecasted reducing pharmacy services.[61]

Although the new CMS rule concededly does not eliminate *all* 340B funding, members of the *amici* hospital associations are nevertheless concerned that the rule's reimbursement reductions are significant enough that many of these bleak predictions will come to pass. The University of California Health system has warned that the new rule could require shuttering some of the system's infusion and post-transplant centers, or some of its inner-city clinics.[62] MedStar Health, which includes seven hospitals in the District of Columbia and Maryland that participate in the 340B Program, explained that the cuts would "significantly reduce the benefits of the 340B program and harm the very hospitals that serve our most vulnerable citizens."[63] In particular, MedStar noted that the cuts would affect in-home services to more than 3,000 of Washington, D.C.'s most vulnerable elderly patients, an after-hours clinic that provides free health care at a Southeast

[61] *Id.*

[62] Letter from John D. Stobo, Executive Vice President, UC Health System, to Seema Verma, Administrator, Centers for Medicare and Medicaid Services 2 (Sept. 11, 2017) (available from counsel for *amici*).

[63] MedStar Health, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 1 (Sept. 5, 2017).

D.C. homeless shelter, a no-charge clinic for uninsured patients in Baltimore, and other facilities.[64]

These examples are part of the administrative record for the new rule. In preparing this brief, *amici* also separately asked their members to identify programs and services that will suffer as a result of CMS's new rule. Those members identified particular clinics and programs that will likely struggle to stay afloat—or, worse, be forced to close—in the wake of the new rule. A few of these additional examples, drawn from hospital and health systems from every corner of the United States, are illustrative:

- A cancer center in New Mexico stands to lose $9.6 million annually as a result of the cuts. Virtually all of the Center's patients will be impacted by the cuts. The Center is planning to cut clinical programs, outreach programs to communities for cancer prevention and screening, and training for cancer healthcare providers. It has also suspended all planned and actively open hiring and is anticipating terminating 4 physicians and 37 staff members by July 1, 2018.

- A faith-based, not-for-profit hospital in Arkansas uses its nearly $3.4 million dollars in 340B savings each year to fund, *inter alia*, an outpatient infusion center, which provides comprehensive cancer care, chemotherapy, and non-oncology infusion services, and to support multiple charitable care clinics serving over 6,000 patients annually. CMS's cuts will endanger this hospital's ability to provide these vital services to its low-income patients from 75 different Arkansas counties.

- A rural hospital in South Georgia will have to terminate its chemotherapy program without 340B reimbursements. The program

[64] *Id.*

serves 30 or more indigent patients who will now have to travel 45 to 60 miles to get their routine chemotherapy. The cuts to the 340B program will triple the costs of medication and will cause the hospital to reduce service to its most vulnerable rural patients.

- Similarly, a hospital in Vermont will lose the revenue it uses to support its oncology program and may be forced to suspend or close the program as a result of the cuts. Without its program, patients will be forced to travel over an hour by car each way for their treatment.

- In the face of 340B cuts, a health system in Tennessee is being forced to consider significantly reducing the number and types of chemotherapy drugs available on its formularies, closing one or more of its chemotherapy and other high-cost infusion sites, and turning away patients.

- A hospital in upstate New York will not be able to absorb the $4 million in cuts from the CMS rule without curtailing services that are needed by the community it serves. Those services include diabetes treatments, many of which are provided through a program specifically targeted at uninsured or underinsured Latina women for whom English is not their primary language. This program has been a success: the hospital has seen decreases in the number of woman at high risk of developing Type 2 diabetes.

- A medical center in Alabama uses its 340B savings to help pay for oral chemotherapy drugs used to treat several types of cancer, including colon cancer, breast cancer, and gallbladder cancer. Without the 340B program, the medical center would not be able to afford this medication for all of its patients, forcing it to pick and choose who receives care.

The list could go on and on. Covered entities in every one of the *amici* hospital associations could identify a specific program or clinic that is threatened by the impending 340B reductions. If *amici*'s fears are realized, and covered entities nationwide are forced to shutter facilities and slash services, the impact will be deeply felt in communities across the country.

IV. CMS'S JUSTIFICATIONS FOR THE DRAMATIC CUTS TO THE 340B PROGRAM LACK MERIT

CMS justifies its drastic reduction to hospital payments for Part B drugs acquired under the 340B Drug Pricing Program by contending that the rule will reduce Medicare beneficiaries' copayments when seeking care from 340B hospitals, and by suggesting that the rule is necessary to avoid the overutilization of costly drugs by 340B hospitals.[65] Neither justification withstands scrutiny nor outweighs the many harms that will result from the new rule. As such, the balance of equities and public interest strongly weigh in favor of a preliminary injunction pending remand.

CMS's contention that Medicare beneficiaries will benefit from reduced drug copayments is misleading. It is true that lowering the reimbursement rate for Part B drugs will impact the associated copayments for those drugs. But contrary to CMS's suggestion, the majority of Medicare beneficiaries will *not* receive a direct benefit. A MedPac analysis demonstrated that 86 percent of all Medicare beneficiaries have supplemental coverage that covers their copayments, and 30 percent of those individuals have their copayments paid for by a public program such as Medicaid.[66] Because the majority of Medicare beneficiaries who seek

[65] 82 Fed. Reg. 52,356, 52,498 (Nov. 13, 2017).

[66] Medicare Payment Advisory Commission, *A Data Book: Healthcare Spending and the Medicare Program* 27 (June 2016),

treatment from 340B hospitals do not actually pay their own copayments, CMS's 340B payment reduction proposal will not benefit most Medicare beneficiaries. Moreover, because the redistributions that result from budget neutrality would increase reimbursement for other services, Medicare beneficiaries who pay their own copayments may actually see *increases* in out of pocket costs for other non-drug outpatient prospective patient payment system ("OPPS") services. One analysis of the new rule found that only 3 percent of beneficiaries being treated at 340B hospitals would see their copayments reduced overall, whereas 97 percent would see their copayment increase.[67] CMS has never directly addressed, let alone refuted, these compelling facts.

Similarly, CMS's concern that "the current payment methodology may lead to unnecessary utilization and potential overutilization of separately payable drugs" is based on flawed studies and incomplete data.[68] HHS itself critiqued the methodology of one of the key studies relied on by CMS, pointing out that the study failed to properly account for the differences in risk profiles for 340B versus

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http://www.medpac.gov/docs/default-source/data-book/june-2016-data-book-health-care-spending-and-the-medicare-program.pdf.

[67] American Hospital Association, Comment Letter on Proposed Rule Change 82 Fed. Reg. 33,558 at 12 (Sept. 11, 2017).

[68] CMS OPPS Proposed Rule, Federal Register, Vol. 82, No. 138, July 20, 2017, p. 33633.

non-340B hospitals.[69] Given the patient population that the 340B Program serves, the higher expenditures for 340B hospitals are more likely a direct consequence of generally sicker beneficiaries at 340B hospitals.[70] The new rule does not account for this common sense reality when imposing its indiscriminate cuts.

In addition, it is far more likely that higher overall drug prices, and not differential utilization by 340B and non-340B hospitals, is the primary driver of increased Medicare Part B drug expenditures. That conclusion is consistent with CMS' own projections.[71] CMS projects average annual increases of 6.4 percent from 2017 to 2025, particularly as a result of high-cost specialty drugs. These trends suggest that a more comprehensive solution is needed than one that haphazardly targets only 340B and its vulnerable patients.

CONCLUSION

In evaluating the district court's denial of a preliminary injunction, this Court must consider the extent to which an injunction is necessary to avert irreparable harm, the balance of the equities, and whether an injunction will serve

[69] U.S. Gov't Accountability Office, GAO-15-442, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 37 (June 2015), https://www.gao/gov/assets/680/670676.pdf ("GAO Report").

[70] GAO Report at p. 37.

[71] See Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2015-2025*, https://www.cms.gov/Research-Statistics-

the public interest.[72] It is difficult to imagine a case that more obviously satisfies those criteria. The new CMS rule will hobble the ability of hospitals throughout the United States to provide health care to vulnerable populations and, in turn, will jeopardize the lives and health of countless needy patients. For these reasons, *amici* respectfully urge the Court to reverse the District Court's decision.

Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2015.pdf.

[72] *League of Women Voters v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016).

February 22, 2018

By: */s/Chad I. Golder*

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CERTIFICATE OF COMPLIANCE

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February 22, 2018 *<u>/s/ Chad I. Golder</u>*
Chad I. Golder

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2018, I caused a true and correct copy of the foregoing to be served on all counsel of record through the Court's CM/ECF system.

February 22, 2018 */s/ Chad I. Golder*
Chad I. Golder

ADDENDUM

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and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and

(J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;

(7) provide 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator,[1] assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals,[2] nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 300jj of this title) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 280j–2 of this title.

(d) Requirement for primary care providers

A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

[1] So in original. The comma probably should be ''and''.

[2] So in original. Probably should be ''hospital,''.

(e) Reporting to Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out by the entity under subsection (c).

(f) Definition of primary care

In this section, the term ''primary care'' means the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

(Pub. L. 111–148, title III, § 3502, title X, § 10321, Mar. 23, 2010, 124 Stat. 513, 952.)

REFERENCES IN TEXT

Section 2703, referred to in subsec. (b)(5), means section 2703 of Pub. L. 111–148.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (c)(2)(A). Pub. L. 111–148, § 10321, inserted ''or other primary care providers'' after ''physicians''.

SUBPART VII—DRUG PRICING AGREEMENTS

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price''), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the ''rebate percent-

age'' is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the ''rebate percentage'' shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term ''over the counter drug'' means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) "Covered entity" defined

In this section, the term ''covered entity'' means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)]).

(B) An entity receiving a grant under section 256a[1] of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II[1] of part C of subchapter XXIV of this chapter (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV of this chapter.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV of this chapter (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2)[1] of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

[1] See References in Text note below.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. 1396r–8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C. 1396r–8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[2] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[2] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C. 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

(1) In general

In this section, the terms ''average manufacturer price'', ''covered outpatient drug'', and

[2] So in original. Probably should be ''subparagraph''.

''manufacturer'' have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. 1396r–8(k)].

(2) Covered drug

In this section, the term ''covered drug''—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act [42 U.S.C. 1396r–8(k)(2)]); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act [42 U.S.C. 1396r–8(k)(3)(A)], a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub. L. 111–152, title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).[1]

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[3] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may

[3] So in original. Probably should be ''subsection''.

be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term ''covered outpatient drug'' shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition.

(July 1, 1944, ch. 373, title III, § 340B, as added Pub. L. 102–585, title VI, § 602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub. L. 103–43, title XX, § 2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub. L. 111–148, title II, § 2501(f)(1), title VII, §§ 7101(a)–(d), 7102, Mar. 23, 2010, 124 Stat. 309, 821–823; Pub. L. 111–152, title II, § 2302, Mar. 30, 2010, 124 Stat. 1082; Pub. L. 111–309, title II, § 204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1), (3), (4)(L)(i), (5)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§ 301 et seq.) of this title. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 256a of this title, referred to in subsec. (a)(4)(B), was in the original a reference to section 340A of act July 1, 1944, which was repealed by Pub. L. 104–299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645. Subsequently, a new section 340A was added to the act of July 1, 1944, by Pub. L. 109–18, § 2, June 29, 2005, 119 Stat. 340, which is also classified to section 256a of this title.

Subpart II of part C of subchapter XXIV of this chapter, referred to in subsec. (a)(4)(D), was redesignated subpart I of part C of subchapter XXIV of this chapter by Pub. L. 106–345, title III, § 301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff–51 et seq. of this title.

The Native Hawaiian Health Care Act of 1988, referred to in subsec. (a)(4)(H), was Pub. L. 100–579, Oct. 31, 1988, 102 Stat. 2916, and subtitle D of title II of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4222, which were classified generally to chapter 122 (§ 11701 et seq.) of this title prior to being amended generally and renamed the Native Hawaiian Health Care Improvement Act by Pub. L. 102–396. For complete classification of this Act to the Code, see Tables.

The Indian Health Care Improvement Act, referred to in subsec. (a)(4)(I), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, as amended. Title V of the Act is classified generally to subchapter IV (§ 1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

Section 247b(j)(2) of this title, referred to in subsec. (a)(4)(K), was repealed and section 247b(j)(1)(B) was redesignated section 247b(j)(2) by Pub. L. 103–183, title III, § 301(b)(1)(A), (C), Dec. 14, 1993, 107 Stat. 2235.

The Prescription Drug Marketing Act, referred to in subsec. (d)(2)(B)(v)(III), probably means the Prescription Drug Marketing Act of 1987, Pub. L. 100–293, Apr. 22, 1988, 102 Stat. 95, which amended sections 331, 333, 353, and 381 of Title 21, Food and Drugs, and enacted provisions set out as notes under sections 301 and 353 of Title 21. For complete classification of this Act to the Code, see Short Title of 1988 Amendments note set out under section 301 of Title 21 and Tables.

CODIFICATION

Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to section 256c of this title.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' and ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, § 7102(b)(1), inserted at end ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

Subsec. (a)(2)(A). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug'' in introductory provisions.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug'' in introductory provisions.

Subsec. (a)(2)(B)(i). Pub. L. 111–148, § 2501(f)(1)(A), substituted ''1927(c)(3)'' for ''1927(c)(4)''.

Subsec. (a)(4)(L). Pub. L. 111–152, § 2302(1)(B), struck out ''and'' at end of cl. (i), substituted ''; and'' for period at end of cl. (ii), and added cl. (iii).

Pub. L. 111–148, § 7101(c)(1), in cl. (i), inserted ''and'' at end, in cl. (ii), substituted period for ''; and'' at end, and struck out cl. (iii) which read as follows: ''does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.''

Subsec. (a)(4)(M) to (O). Pub. L. 111–148, § 7101(a), added subpars. (M) to (O).

Subsec. (a)(5)(B). Pub. L. 111–152, § 2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, § 7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C). Pub. L. 111–152, § 2302(1)(C)(i), (ii), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) read as follows:

''(i) IN GENERAL.—A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

''(ii) INPATIENT DRUGS.—Clause (i) shall not apply to drugs purchased for inpatient use.

''(iii) EXCEPTIONS.—The Secretary shall establish reasonable exceptions to clause (i)—

''(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;

''(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; or

''(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

''(iv) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.—The Secretary shall ensure that a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section shall have multiple options for purchasing covered outpatient drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer,

and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.''

Pub. L. 111–148, §7101(c)(2)(B), added subpar. (C). Former subpar. (C) redesignated (D).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(C)(iv). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Subsec. (a)(5)(D). Pub. L. 111–152, §2302(1)(C)(ii), (iii), redesignated subpar. (E) as (D) and substituted ''subparagraph (C)'' for ''subparagraph (D)''. Former subpar. (D) redesignated (C).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §7101(c)(2)(A), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Pub. L. 111–148, §7101(b)(1), substituted ''covered drug'' for ''covered outpatient drug''.

Subsec. (a)(5)(E). Pub. L. 111–152, §2302(1)(C)(ii), redesignated subpar. (E) as (D).

Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drug'' for ''covered drug''.

Pub. L. 111–148, §§7101(c)(2)(A), 7102(b)(2), redesignated subpar. (D) as (E) and inserted ''after audit as described in subparagraph (D) and'' after ''finds,''.

Subsec. (a)(7). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs'' wherever appearing.

Subsec. (a)(9). Pub. L. 111–152, §2302(1)(A), substituted ''covered outpatient drugs'' for ''covered drugs''.

Pub. L. 111–148, §7101(b)(1), substituted ''covered drugs'' for ''covered outpatient drugs''.

Subsec. (b). Pub. L. 111–148, §7101(b)(2)(A), which directed substitution of ''Other definitions'' for ''Other definition'' in subsec. heading, designation of existing provisions as par. (1), and insertion of par. (1) heading, was executed by reenacting subsec. heading without change, designating existing provisions as par. (1), and inserting par. (1) heading, to reflect the probable intent of Congress.

Subsec. (b)(2). Pub. L. 111–148, §7101(b)(2)(B), added par. (2).

Subsec. (c). Pub. L. 111–152, §2302(2), struck out subsec. (c). Text read as follows: ''Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.''

Pub. L. 111–148, §7101(d), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: ''A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992.''

Pub. L. 111–148, §2501(f)(1)(B), (C), redesignated subsec. (d) as (c) and struck out former subsec. (c). Text of former subsec. (c) read as follows: ''Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on November 4, 1992.''

Subsec. (d). Pub. L. 111–152, §2302(3), substituted ''covered outpatient drugs'' for ''covered drugs'' wherever appearing and substituted ''(a)(5)(C)'' for ''(a)(5)(D)'' and ''(a)(5)(D)'' for ''(a)(5)(E)'' in two places.

Pub. L. 111–148, §7102(a), which directed general amendment of subsec. (d), was executed by adding subsec. (d) after subsec. (c) to reflect the probable intent of Congress, because no subsec. (d) appeared subsequent to amendment by Pub. L. 111–148, §2501(f)(1)(C). See below.

Pub. L. 111–148, §2501(f)(1)(C), redesignated subsec. (d) as (c).

Subsec. (e). Pub. L. 111–309 substituted ''covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M))'' for ''covered entities described in subparagraph (M)''.

Pub. L. 111–152, §2302(4), added subsec. (e).

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–585, §602(a), which enacted this section.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–309, title II, §204(a)(2), Dec. 15, 2010, 124 Stat. 3289, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152).''

Pub. L. 111–148, title II, §2501(f)(2), Mar. 23, 2010, 124 Stat. 310, provided that: ''The amendments made by this subsection [amending this section] take effect on January 1, 2010.''

Pub. L. 111–148, title VII, §7101(e), Mar. 23, 2010, 124 Stat. 823, provided that:

''(1) IN GENERAL.—The amendments made by this section [amending this section] and section 7102 [amending this section] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

''(2) EFFECTIVENESS.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.''

STUDY OF TREATMENT OF CERTAIN CLINICS AS COVERED ENTITIES ELIGIBLE FOR PRESCRIPTION DRUG DISCOUNTS

Section 602(b) of Pub. L. 102–585 directed Secretary of Health and Human Services to conduct a study of feasibility and desirability of including specified entities receiving funds from a State as covered entities eligible for limitations on prices of covered outpatient drugs under 42 U.S.C. 256b(a) and, not later than 1 year after Nov. 4, 1992, to submit a report to Congress on the study, including in the report a description of the entities that were the subject of the study, an analysis of the extent to which such entities procured prescription drugs, and an analysis of the impact of the inclusion of such entities as covered entities on the quality of care provided to and the health status of the patients of such entities.

SUBPART VIII—BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

AMENDMENTS

1993—Pub. L. 103–43, title XX, §2008(i)(2)(A)(i), June 10, 1993, 107 Stat. 213, made technical amendment relating to placement of subpart VIII within part D of this subchapter.

§ 256c. Bulk purchases of vaccines for certain programs

(a) Agreements for purchases

(1) In general

Not later than 180 days after October 27, 1992, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations

Title 42—Public Health

(This book contains parts 400 to 429)

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 62 FR 46037, Aug. 29, 1997; 66 FR 39452, July 31, 2001; and 67 FR 36540, May 24, 2002.

SUBCHAPTER A—GENERAL PROVISIONS

SUBCHAPTER B—MEDICARE PROGRAM

that furnished services were excluded from coverage as not reasonable and necessary if one or more of the conditions in §411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2) of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this section.* A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

Subpart A—General Provisions

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

Subpart E—Determination of Transition Period Payment Rates for the Prospective Payment System for Inpatient Operating Costs

part. This adjustment is set forth in § 412.102.

(2) CMS establishes a procedure by which certain individual hospitals located in urban areas may apply for reclassification as rural. The criteria for reclassification are set forth in § 412.103.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* CMS makes an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1, 1984 are ESRD beneficiary discharges. In determining ESRD discharges, discharges in DRG Nos. 302, 316, and 317 are excluded. The criteria for this additional payment are set forth in § 412.104.

(g) *Hosptials that incur indirect costs for graduate medical education programs.* CMS makes an additional payment for inpatient operating costs to a hospital for indirect medical education costs attributable to an approved graduate medical education program. The criteria for this additional payment are set forth in § 412.105.

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1, 1986, CMS makes an additional payment for inpatient operating costs to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

(i) *Hospitals that receive an additional update for FYs 1998 and 1999.* For FYs 1998 and 1999, CMS makes an upward adjustment to the standardized amounts for certain hospitals that do not receive indirect medical education or disproportionate share payments and are not Medicare- dependent, small rural hospitals. The criteria for identifying these hospitals are set forth in § 412.107.

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997, and before October 1, 2011, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

(k) *Essential access community hospitals (EACHs).* If a hospital was designated as an EACH by CMS as described in § 412.109(a) and is located in a rural area as defined in § 412.109(b), CMS determines the prospective payment rate for that hospital, as it does for sole community hospitals, under § 412.92(d).

[57 FR 39823, Sept. 1, 1992, as amended at 58 FR 30669, May 26, 1993; 62 FR 46028, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999; 65 FR 47047, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005; 71 FR 48138, Aug. 18, 2006]

§ 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals

but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

(b) *Classification procedures*—(1) *Request for classification as sole community hospital.* (i) The hospital must make its request to its fiscal intermediary.

(ii) If a hospital is seeking sole community hospital classification under paragraph (a)(1)(i) or (a)(1)(ii) of this section, the hospital must include the following information with its request:

(A) The hospital must provide patient origin data (for example, the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area.

(B) The hospital must provide patient origin data from all other hospitals located within a 35 mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care.

(iii)(A) If the hospital is unable to obtain the information required under paragraph (b)(1)(ii)(A) of this section concerning the residences of Medicare beneficiaries who were inpatients in other hospitals located within a 35 mile radius of the hospital or, if larger, within the hospital's service area, the hospital may request that CMS provide this information.

(B) If a hospital obtains the information as requested under paragraph (b)(1)(iii)(A) of this section, that information is used by both the intermediary and CMS in making the determination of the residences of Medicare beneficiaries under paragraphs (b)(1)(iii) and (b)(1)(iv) of this section, regardless of any other information concerning the residences of Medicare beneficiaries submitted by the hospital.

(iv) The intermediary reviews the request and send the request, with its recommendation, to CMS.

(v) CMS reviews the request and the intermediary's recommendation and forward its approval or disapproval to the intermediary.

(2) *Effective dates of classification.* (i) Sole community hospital status is effective 30 days after the date of CMS's written notification of approval.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses an CMS denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

(A) If the hospital's application was submitted prior to October 1, 1983, its status as a sole community hospital is effective at the start of the cost reporting period for which it sought exemption from the cost limits.

(B) If the hospital's application for sole community hospital status was filed on or after October 1, 1983, the effective date is 30 days after the date of CMS's original written notification of denial.

(iii) When a hospital is granted retroactive approval of sole community hospital status by a court order or a PRRB decision and the hospital wishes its sole community hospital status terminated before the date of the court order or PRRB determination, it must submit written notice to the CMS regional office within 90 days of the court order or PRRB decision. A written request received after the 90-day period is effective no later than 30 days after the request is submitted.

(iv) A hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS's approval of the classification.

(3) *Duration of classification.* (i) An approved classification as a sole community hospital remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. An approved sole community hospital must notify the fiscal intermediary if

any change that is specified in paragraph (b)(3)(ii) of this section occurs. If CMS determines that a sole community hospital failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date that the hospital no longer met the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(ii) A sole community hospital must report the following to the fiscal intermediary within 30 days of the event:

(A) The opening of a new hospital in its service area.

(B) The opening of a new road between itself and a like provider within 35 miles.

(C) An increase in the number of beds to more than 50 if the hospital qualifies as a sole community hospital under paragraph (a)(1)(ii) of this section.

(D) Its geographic classification changes.

(E) Any changes to the driving conditions that result in a decrease in the amount of travel time between itself and a like provider if the hospital qualifies as a sole community hospital under paragraph (a)(3) of this section.

(iii) A sole community hospital must report to the fiscal intermediary if it becomes aware of any change that would affect its classification as a sole community hospital beyond the events listed in paragraph (b)(3)(ii) of this section within 30 days of the event. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date the hospital became aware of the event that resulted in the sole community hospital no longer meeting the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(4) *Cancellation of classification.* (i) A hospital may at any time request cancellation of its classification as a sole community hospital, and be paid at rates determined under subparts D and E of this part, as appropriate.

(ii) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(iii) If a hospital requests that its sole community hospital classification be cancelled, it may not be reclassified as a sole community hospital unless it meets the following conditions:

(A) At least one full year has passed since the effective date of its cancellation.

(B) The hospital meets the qualifying criteria set forth in paragraph (a) of this section in effect at the time it reapplies.

(5) *Automatic classification as a sole community hospital.* A hospital that has been granted an exemption from the hospital cost limits before October 1, 1983, or whose request for the exemption was received by the appropriate intermediary before October 1, 1983, and was subsequently approved, is automatically classified as a sole community hospital unless that classification has been cancelled under paragraph (b)(3) of this section, or there is a change in the circumstances under which the classification was approved.

(c) *Terminology.* As used in this section—

(1) The term *miles* means the shortest distance in miles measured over improved roads. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road includes the paved surface up to the front entrance of the hospital.

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

(3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for

classification as a sole community hospital.

(d) *Determining prospective payment rates for inpatient operating costs for sole community hospitals*—(1) *General rule.* For cost reporting periods beginning on or after April 1, 1990, a sole community hospital is paid based on whichever of the following amounts yields the greatest aggregate payment for the cost reporting period:

(i) The Federal payment rate applicable to the hospitals as determined under subpart D of this part.

(ii) The hospital-specific rate as determined under §412.73.

(iii) The hospital-specific rate as determined under §412.75.

(iv) For cost reporting periods beginning on or after October 1, 2000, the hospital-specific rate as determined under §412.77 (calculated under the transition schedule set forth in paragraph (d)(2) of this section).

(2) *Transition of FY 1996 hospital-specific rate.* The intermediary calculates the hospital-specific rate determined on the basis of the fiscal year 1996 base period rate as follows:

(i) For Federal fiscal year 2001, the hospital-specific rate is the sum of 75 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 25 percent of the hospital-specific rate as determined under §412.77.

(ii) For Federal fiscal year 2002, the hospital-specific rate is the sum of 50 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 50 percent of the hospital-specific rate as determined under §412.77.

(iii) For Federal fiscal year 2003, the hospital-specific rate is the sum of 25 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 75 percent of the hospital-specific rate as determined under §412.77.

(iv) For Federal fiscal year 2004 and any subsequent fiscal years, the hospital-specific rate is 100 percent of the hospital-specific rate specified in paragraph (d)(1)(iv) of this section.

(3) *Adjustment to payments.* A sole community hospital may receive an adjustment to its payments to take into account a significant decrease in the number of discharges, as described in paragraph (e) of this section.

(e) *Additional payments to sole community hospitals experiencing a significant volume decrease.* (1) For cost reporting periods beginning on or after October 1, 1983, the intermediary provides for a payment adjustment for a sole community hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (e)(2) of this section a more than five percent decrease in its total discharges of inpatients as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the intermediary must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a sole community hospital must submit its request no later than 180 days after the date on the intermediary's Notice of Amount of Program Reimbursement—

(i) Submit to the intermediary documentation demonstrating the size of the decrease in discharges, and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) The intermediary determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under §412.106 and for indirect medical education costs as determined under §412.105).

(i) In determining the adjustment amount, the intermediary considers—

(A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) The intermediary makes its determination within 180 days from the date it receives the hospital's request and all other necessary information.

(iii) The intermediary determination is subject to review under subpart R of part 405 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 51 FR 34793, Sept. 30, 1986; 52 FR 30367, Aug. 14, 1987; 52 FR 33057, Sept. 1, 1987; 53 FR 38529, Sept. 30, 1988; 54 FR 36494, Sept. 1, 1989; 55 FR 14283, Apr. 17, 1990; 55 FR 15174, Apr. 20, 1990; 55 FR 36070, Sept. 4, 1990; 56 FR 25487, June 4, 1991; 57 FR 39823, Sept. 1, 1992; 60 FR 45848, Sept. 1, 1995; 65 FR 47107, Aug. 1, 2000; 66 FR 32193, June 13, 2001; 66 FR 39933, Aug. 1, 2001; 67 FR 50111, Aug. 1, 2002; 70 FR 47485, Aug. 12, 2005; 71 FR 48138, Aug. 18, 2006]

§ 412.96 Special treatment: Referral centers.

(a) *Criteria for classification as a referral center: Basic rule.* CMS classifies a hospital as a referral center only if the hospital is a Medicare participating acute care hospital and meets the applicable criteria of paragraph (b) or (c) of this section.

(b) *Criteria for cost reporting periods beginning on or after October 1, 1983.* The hospital meets either of the following criteria:

(1) The hospital is located in a rural area (as defined in subpart D of this part) and has the following number of beds, as determined under the provisions of § 412.105(b) available for use:

(i) Effective for discharges occurring before April 1, 1988, the hospital has 500 or more beds.

(ii) Effective for discharges occurring on or after April 1, 1988, the hospital has 275 or more beds during its most recently completed cost reporting period unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of the following reasons:

(A) Merger of two or more hospitals.

(B) Reopening of acute care beds previously closed for renovation.

(C) Transfer to the prospective payment system of acute care beds previously classified as part of an excluded unit.

(D) Expansion of acute care beds available for use and permanently maintained for lodging inpatients, excluding beds in corridors and other temporary beds.

(2) The hospital shows that—(i) At least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the staff of the hospital; and

(ii) At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital, and at least 60 percent of all the services that the hospital furnishes to Medicare beneficiaries are furnished to beneficiaries who live more than 25 miles from the hospital.

(c) *Alternative criteria.* For cost reporting periods beginning on or after October 1, 1985, a hospital that does not meet the criteria of paragraph (b) of this section is classified as a referral center if it is located in a rural area (as defined in subpart D of this part) and meets the criteria specified in paragraphs (c)(1) and (c)(2) of this section and at least one of the three criteria specified in paragraphs (c)(3), (c)(4), and (c)(5) of this section.

(1) *Case-mix index.* CMS sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (h) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by CMS from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to CMS. The hospital's case-mix index for discharges (not including discharges from units excluded from the prospective payment system

tion in subsection (b)(2)(B) by adding cl. (iii) at the end, was executed by adding cl. (iii) at the end of subsec. (b)(2)(B) to reflect the probable intent of Congress.

Subsec. (b)(3)(B). Pub. L. 101–508, §4716(a)(3), which directed amendment of subsection (f) of this section in subsection (b)(3)(B) by inserting at the end ''No such termination shall be effective earlier than 10 days after the date of mailing of such notice.'', was executed by making the insertion at the end of subsec. (b)(3)(B) to reflect the probable intent of Congress.

Subsec. (b)(3)(C)(i). Pub. L. 101–508, §4601(a)(3)(B), inserted ''(i)(VII),'' after ''(i)(VI)''.

1989—Subsec. (a)(3)(A). Pub. L. 101–239, §6411(i)(1), substituted ''a child, whether or not the child is'' for ''a child who is''.

Subsec. (a)(3)(C). Pub. L. 101–239, §6411(i)(3), substituted ''of section 1396d(a) of this title or clause (i)(IV), (i)(VI), or (ii)(IX) of section 1396a(a)(10)(A) of this title'' for ''or (v) of section 1396d(a) of this title''.

Subsec. (b)(3)(A)(i). Pub. L. 101–239, §6411(i)(1), substituted ''a child, whether or not the child is'' for ''a child who is''.

Subsec. (b)(3)(C)(i). Pub. L. 101–239, §6411(i)(3), substituted ''of section 1396d(a) of this title or clause (i)(IV), (i)(VI), or (ii)(IX) of section 1396a(a)(10)(A) of this title'' for ''or (v) of section 1396d(a) of this title''.

1988—Subsec. (b)(5)(C). Pub. L. 100–647, which directed the amendment of subsec. (d)(5)(C) by inserting ''(less the average monthly costs for such child care as is necessary for the employment of the caretaker relative)'' after ''gross monthly earnings'', was executed to subsec. (b)(5)(C) to reflect the probable intent of Congress.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–40 effective July 1, 2003, see section 8 of Pub. L. 108–40, set out as a note under section 603 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4701(b)(2)(A)(ix), (D) of Pub. L. 105–33 effective Aug. 5, 1997, and applicable to contracts entered into or renewed on or after Oct. 1, 1997, see section 4710(a) of Pub. L. 105–33, set out as a note under section 1396b of this title.

Amendment by section 4703(b)(2) of Pub. L. 105–33 applicable to contracts under section 1396b(m) of this title on and after June 20, 1997, subject to provisions relating to extension of effective date for State law amendments, and to nonapplication to waivers, see section 4710(b)(2) of Pub. L. 105–33, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–193 effective July 1, 1997, with transition rules relating to State options to accelerate such date, rules relating to claims, actions, and proceedings commenced before such date, rules relating to closing out of accounts for terminated or substantially modified programs and continuance in office of Assistant Secretary for Family Support, and provisions relating to termination of entitlement under AFDC program, see section 116 of Pub. L. 104–193, as amended, set out as an Effective Date note under section 601 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4601(a)(3)(B) of Pub. L. 101–508 applicable, except as otherwise provided, to payments under this subchapter for calendar quarters beginning on or after July 1, 1991, without regard to whether or not final regulations to carry out the amendments by section 4601 of Pub. L. 101–508 have been promulgated by such date, see section 4601(b) of Pub. L. 101–508, set out as a note under section 1396a of this title.

Section 4716(b) of Pub. L. 101–508 provided that: ''The amendments made by subsection (a) [amending this section] shall be effective as if included in the enactment of the Family Support Act of 1988 [Pub. L. 100–485].''

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6411(i)(4) of Pub. L. 101–239 provided that: ''The amendments made by this subsection [amending this section and provisions set out as a note under section 602 of this title] shall be effective as if included in the enactment of the Family Support Act of 1988 [Pub. L. 100–485].''

EFFECTIVE DATE OF 1988 AMENDMENT

Section 8436(b) of Pub. L. 100–647 provided that: ''The amendment made by subsection (a) [amending this section] shall be effective as if included in the enactment of the Family Support Act of 1988 [Pub. L. 100–485].''

EFFECTIVE DATE

Section applicable to payments under this subchapter for calendar quarters beginning on or after Apr. 1, 1990 (or, in the case of the Commonwealth of Kentucky, Oct. 1, 1990) (without regard to whether implementing regulations are promulgated by that date), with respect to families that cease to be eligible for aid under part A of subchapter IV of this chapter on or after that date, see section 303(f)(1) of Pub. L. 100–485, set out as an Effective Date of 1988 Amendment note under section 1396a of this title.

REFERENCES TO PROVISIONS OF PART A OF SUBCHAPTER IV CONSIDERED REFERENCES TO SUCH PROVISIONS AS IN EFFECT JULY 16, 1996

For provisions that certain references to provisions of part A (§601 et seq.) of subchapter IV of this chapter be considered references to such provisions of part A as in effect July 16, 1996, see section 1396u–1(a) of this title.

STUDY AND REPORT TO CONGRESS ON IMPACT OF MEDICAID EXTENSION PROVISIONS

Section 303(c) of Pub. L. 100–485 directed Secretary of Health and Human Services to conduct a study of impact of medicaid extension provisions under this section, with particular focus on costs of such provisions and impact on welfare dependency, and report to Congress on results of such study not later than Apr. 1, 1993.

§1396r–7. Repealed. Pub. L. 105–33, title IV, §4713(a), Aug. 5, 1997, 111 Stat. 509

Section, act Aug. 14, 1935, ch. 531, title XIX, §1926, as added Dec. 19, 1989, Pub. L. 101–239, title VI, §6402(b), 103 Stat. 2260, related to adequate payment levels for obstetrical and pediatric services.

EFFECTIVE DATE OF REPEAL

Section 4713(b) of Pub. L. 105–33 provided that: ''The repeal made by subsection (a) [repealing this section] shall apply to services furnished on or after October 1, 1997.''

§1396r–8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII of this chapter for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month

that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1–A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section, or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) "Covered entity" defined

In this subsection, the term ''covered entity'' means an entity described in section 256b(a)(4) of this title and a children's hospital described in section 1395ww(d)(1)(B)(iii) of this title which meets the requirements of clauses (i) and (iii) of section 256b(b)(4)(L)[1] of this title and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this subchapter.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) of this section with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under

[1] See References in Text note below.

such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(7) Requirement for submission of utilization data for certain physician administered drugs

(A) Single source drugs

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a single source drug that is physician administered under this subchapter (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this subchapter.

(B) Multiple source drugs

(i) Identification of most frequently physician administered multiple source drugs

Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this subchapter. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) Requirement

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) Use of NDC codes

Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) Hardship waiver

The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)]); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990[2] for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1395w–3a(c) of this title) and the total number of units specified under section 1395w–3a(b)(2)(A) of this title;

(II) if required to make payment under section 1395w–3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1395w–3a(c)(2)(B) of this title;

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1395u(*o*)(1) of this title or section 1395rr(b)(13)(A)(ii) of this title, and, for calendar quarters beginning on or after January 1, 2007[2] and only with respect to the information described in subclause (III), for covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).

(B) Verification surveys of average manufacturer price and manufacturer's average sales price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a–7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by

[2] So in original. Probably should be followed by a comma.

law. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section (other than the wholesale acquisition cost for purposes of carrying out section 1395w–3a of this title) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1395w–3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w–3b of this title,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this subchapter, and

(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.

The previous sentence shall also apply to information disclosed under section 1395w–102(d)(2) or 1395w–104(c)(2)(E) of this title and drug pricing data reported under the first sentence of section 1395w–141(i)(1) of this title.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the ''minimum rebate percentage'' for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) "Best price" defined

For purposes of this section—

(i) In general

The term ''best price'' means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w–141 of this title; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII of this chapter, by an MA–PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter.

(ii) Special rules

The term ''best price''—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)], shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) Application of auditing and recordkeeping requirements

With respect to a covered entity described in section 256b(a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b(a)(5)(C) of this title.

(D) Limitation on sales at a nominal price

(i) In general

For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 256b(a)(4) of this title.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) Factors

The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) Nonapplication

Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting ''the first full calendar quarter after the day on which the drug was first marketed'' for ''the calendar quarter beginning July 1, 1990'' and ''the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed'' for ''September 1990''.

(3) Rebate for other drugs

(A) In general

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) "Applicable percentage" defined

For purposes of subparagraph (A)(i), the ''applicable percentage'' for rebate periods beginning—

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined,

based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this subchapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)][3] Establishment of upper payment limits

Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more (or, effective January 1, 2007, two or more) products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) Use of amp in upper payment limits

Effective January 1, 2007, in applying the Federal upper reimbursement limit under

[3] See 1993 Amendment note below.

paragraph (4)[4] and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.

(f) Survey of retail prices; State payment and utilization rates; and performance rankings

(1) Survey of retail prices

(A) Use of vendor

The Secretary may contract services for—

(i) the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) Secretary response to notification of availability of multiple source products

If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).[4]

(C) Use of competitive bidding

In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Additional provisions

A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) Availability of information to States

Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1396a(a)(5) of this title with responsibility for the administration or supervision of the administration of the State plan under this subchapter of the retail survey price determined under this paragraph.

(2) Annual State report

Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this subchapter for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) Annual State performance rankings

(A) Comparative analysis

The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this subchapter for each such drug for each State.

(B) Availability of information

The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) Appropriation

Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic ap-

[4] See References in Text note below.

propriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[5]

[5] So in original. Probably should be ''paragraph''.

(1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the ''DUR Board'') either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least ⅓ but no more than 51 percent licensed and actively practicing physicians and at least ⅓ * * *[6] licensed and actively practicing pharmacists.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[7] (2)(B).

(ii) Application of standards as defined in section[7] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall re-

[6] So in original.

[7] So in original. Probably should be ''paragraph''.

ceive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Omitted

(j) Exemption of organized health care settings

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) of this title, are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions

In this section—

(1) Average manufacturer price

(A) In general

Subject to subparagraph (B), the term ''average manufacturer price'' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

(B) Exclusion of customary prompt pay discounts extended to wholesalers

The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.

(C) Inclusion of section 505(c) drugs

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)], such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term ''covered outpatient drug'' means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 [21 U.S.C. 355] or 507[8] of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act [21 U.S.C. 355(j)];

(ii)(I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C. 331, 332(a), 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C. 352(f), 355(a)]; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506[8] of the Federal Food, Drug, and Cosmetic Act.

(3) Limiting definition

The term ''covered outpatient drug'' does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the fol-

[8] See References in Text note below.

lowing and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological[9] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as ''over-the-counter'' drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term ''manufacturer'' means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term ''medically accepted indication'' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term ''multiple source drug'' means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there[10] at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term ''innovator multiple source drug'' means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term ''noninnovator multiple source drug'' means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term ''single source drug'' means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception

Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

[9] So in original. Probably should be ''biological product''.

[10] So in original. Probably should be followed by ''is''.

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period

The term ''rebate period'' means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term ''State agency'' means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

(Aug. 14, 1935, ch. 531, title XIX, § 1927, as added Pub. L. 101–508, title IV, § 4401(a)(3), Nov. 5, 1990, 104 Stat. 1388–143; amended Pub. L. 102–585, title VI, § 601(a)–(c), Nov. 4, 1992, 106 Stat. 4962–4964; Pub. L. 103–18, § 2(a), Apr. 12, 1993, 107 Stat. 54; Pub. L. 103–66, title XIII, § 13602(a), Aug. 10, 1993, 107 Stat. 613; Pub. L. 105–33, title IV, §§ 4701(b)(2)(A)(x), 4756, Aug. 5, 1997, 111 Stat. 493, 527; Pub. L. 106–113, div. B, § 1000(a)(6) [title VI, §§ 606(a), 608(u)], Nov. 29, 1999, 113 Stat. 1536, 1501A–396, 1501A–398; Pub. L. 108–173, title I, §§ 101(e)(4), (9), 103(e)(1), 105(b), title III, § 303(i)(4), title IX, § 900(e)(1)(K), (L), title X, § 1002, Dec. 8, 2003, 117 Stat. 2151, 2152, 2159, 2166, 2254, 2372, 2431; Pub. L. 109–91, title I, § 104(a), Oct. 20, 2005, 119 Stat. 2092; Pub. L. 109–171, title VI, §§ 6001(a)–(c)(2), (d)–(f)(2), 6002(a), 6003(a), (b), 6004(a), Feb. 8, 2006, 120 Stat. 54–61; Pub. L. 109–432, div. B, title IV, § 405(c)(2)(A)(ii), Dec. 20, 2006, 120 Stat. 3000.)

REFERENCES IN TEXT

Parts A, B, C, and D of subchapter XVIII of this chapter, referred to in subsecs. (a)(1) and (c)(1)(C)(i)(VI), are classified to sections 1395c et seq., 1395j et seq., 1395w–21 et seq., and 1395w–101 et seq., respectively, of this title.

Section 256b(b)(4)(L) of this title, referred to in subsec. (a)(5)(B), probably should be section 256b(a)(4)(L) of this title, relating to a subsection (d) hospital. Section 256b(b) of this title does not contain a par. (4).

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(4)(C) and (k)(6), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Paragraph (4) and subsection (e)(4), referred to in subsecs. (e)(5) and (f)(1)(B), probably means text that was editorially designated as par. (4) of subsec. (e). See 1993 Amendment note below.

Section 507 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (k)(2)(A)(i), was repealed by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

Section 107(c)(3) of the Drug Amendments of 1962, referred to in subsec. (k)(2)(A)(iii)(I), is section 107(c)(3) of Pub. L. 87–781 which is set out in an Effective Date of 1962 Amendment note under section 321 of Title 21, Food and Drugs.

Section 506 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (k)(2)(C), was repealed and a new section 506 enacted by Pub. L. 105–115, title I, §§ 112(a), 125(a)(1), Nov. 21, 1997, 111 Stat. 2309, 2325, which no longer relates to insulin.

CODIFICATION

Subsec. (i) of this section, which required the Secretary to transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives an annual report on the operation of this section in the preceding fiscal year, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, item 9 on page 93 of House Document No. 103–7.

PRIOR PROVISIONS

A prior section 1927 of act Aug. 14, 1935, was renumbered section 1939 and is classified to section 1396v of this title.

AMENDMENTS

2006—Subsec. (a)(5)(B). Pub. L. 109–171, § 6004(a), inserted before period at end ''and a children's hospital described in section 1395ww(d)(1)(B)(iii) of this title which meets the requirements of clauses (i) and (iii) of section 256b(b)(4)(L) of this title and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this subchapter''.

Subsec. (a)(7). Pub. L. 109–171, § 6002(a), added par. (7).

Subsec. (b)(3)(A). Pub. L. 109–171, § 6001(b)(1)(B), inserted ''Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).'' at end of concluding provisions.

Subsec. (b)(3)(A)(i). Pub. L. 109–171, § 6003(a)(1), added cl. (i) and struck out former cl. (i) which read as follows: ''not later than 30 days after the last day of each month of a rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section), customary prompt pay discounts extended to wholesalers, and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement,;''.

Pub. L. 109–171, § 6001(b)(1)(A), (c)(2), inserted ''month of a'' after ''last day of each'' and '', customary prompt pay discounts extended to wholesalers,'' after ''(k)(1) of this section)''.

Subsec. (b)(3)(A)(ii). Pub. L. 109–171, § 6003(a)(2), inserted ''(including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)'' after ''drugs''.

Subsec. (b)(3)(A)(iii). Pub. L. 109–171, § 6001(d)(1), inserted '', and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs'' before period at end.

Subsec. (b)(3)(D)(iv), (v). Pub. L. 109–171, § 6001(b)(2), added cls. (iv) and (v).

Subsec. (c)(1)(C)(i). Pub. L. 109–171, § 6003(b)(1)(A), inserted ''(including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)'' after ''or innovator multiple source drug of a manufacturer'' in introductory provisions.

Subsec. (c)(1)(C)(ii)(IV). Pub. L. 109–171, § 6003(b)(1)(B), added subcl. (IV).

Subsec. (c)(1)(D). Pub. L. 109–171, § 6001(d)(2), added subpar. (D).

Subsec. (e)(4). Pub. L. 109–171, § 6001(a)(1), which directed substitution of ''Subject to paragraph (5), the

Secretary'' for ''The Secretary'' and insertion of ''(or, effective January 1, 2007, two or more)'' after ''three or more'' in subsec. (e)(4), was executed to the last par. of subsec. (e) to reflect the probable intent of Congress. See 1993 Amendment note below.

Subsec. (e)(5). Pub. L. 109–171, §6001(a)(2), added par. (5).

Subsec. (f). Pub. L. 109–171, §6001(e), added subsec. (f).

Subsec. (g)(1)(B)(i)(II). Pub. L. 109–171, §6001(f)(1), which directed insertion of ''(or its successor publications)'' after ''United States Pharmacopoeia-Drug Information'', was executed by making insertion after ''United States Pharmacopeia-Drug Information'' to reflect the probable intent of Congress.

Subsec. (g)(2)(A)(ii). Pub. L. 109–171, §6001(f)(2), inserted '', or to require verification of the offer to provide consultation or a refusal of such offer'' before period at end of concluding provisions.

Subsec. (k)(1). Pub. L. 109–171, §6001(c)(1), designated existing provisions as subpar. (A), inserted heading, substituted ''Subject to subparagraph (B), the term'' for ''The term'', struck out '', after deducting customary prompt pay discounts'' before period at end, and added subpar. (B).

Subsec. (k)(1)(C). Pub. L. 109–171, §6003(b)(2), as amended by Pub. L. 109–432, added subpar. (C).

Subsec. (k)(7)(A)(i). Pub. L. 109–171, §6001(a)(4), substituted ''is'' for ''are'' in subcls. (I), (II), and (III).

Pub. L. 109–171, §6001(a)(3), substituted ''at least 1 other drug product'' for ''are 2 or more drug products'' in introductory provisions.

2005—Subsec. (d)(2)(K). Pub. L. 109–91 added subpar. (K).

2003—Subsec. (a)(1). Pub. L. 108–173, §303(i)(4)(A), inserted ''or under part B of subchapter XVIII of this chapter'' after ''section 1396b(a) of this title''.

Subsec. (b)(3)(A). Pub. L. 108–173, §303(i)(4)(B), added cl. (iii) and concluding provisions.

Subsec. (b)(3)(B). Pub. L. 108–173, §303(i)(4)(C), inserted ''and manufacturer's average sales price'' after ''average manufacturer price'' in heading and ''and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment'' after ''manufacturer prices'' in text.

Subsec. (b)(3)(D). Pub. L. 108–173, §303(i)(4)(D)(i), inserted ''(other than the wholesale acquisition cost for purposes of carrying out section 1395w–3a of this title)'' after ''subsection (a)(6)(A)(ii) of this section'' in introductory provisions.

Pub. L. 108–173, §105(b), which directed insertion of ''and drug pricing data reported under the first sentence of section 1395w–141(i)(1) of this title'' after ''section 1395w–104(c)(2)(E) of this title'' in last sentence, was executed by making the insertion after ''or 1395w–104(c)(2)(E) of this title'' in concluding provisions to reflect the probable intent of Congress.

Pub. L. 108–173, §101(e)(4), inserted concluding provisions.

Subsec. (b)(3)(D)(i). Pub. L. 108–173, §303(i)(4)(D)(ii), inserted '', to carry out section 1395w–3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w–3b of this title'' after ''this section''.

Subsec. (c)(1)(C)(i)(I). Pub. L. 108–173, §1002(a), inserted ''(including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title)'' before semicolon at end.

Subsec. (c)(1)(C)(i)(V), (VI). Pub. L. 108–173, §103(e)(1), added subcls. (V) and (VI).

Subsec. (c)(1)(C)(iii). Pub. L. 108–173, §1002(b), added cl. (iii).

Subsec. (e)[(4)]. Pub. L. 108–173, §900(e)(1)(K), (L), which directed substitution of ''The Secretary'' for ''HCFA'' in subsecs. (e)(4) and (f)(2), was executed to the last par. of subsec. (e) to reflect the probable intent of Congress. See 1993 Amendment note below.

Subsec. (g)(1)(B)(i)(II). Pub. L. 108–173, §101(e)(9)(A), inserted ''and'' at end.

Subsec. (g)(1)(B)(i)(IV). Pub. L. 108–173, §101(e)(9)(B), struck out subcl. (IV) which read as follows: ''American Medical Association Drug Evaluations; and''.

1999—Subsec. (a)(1). Pub. L. 106–113, §1000(a)(6) [title VI, §606(a)], substituted ''shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before'' for ''shall not be effective until''.

Subsec. (g)(2)(A)(ii)(II)(cc). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(1)], substituted ''individual's'' for ''individuals''.

Subsec. (i)(1). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(2)], substituted ''the operation of this section'' for ''the the operation of this section''.

Subsec. (k)(7)(A)(iv). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(3)(A)], substituted ''distributors'' for ''distributers''.

Subsec. (k)(7)(C)(i). Pub. L. 106–113, §1000(a)(6) [title VI, §608(u)(3)(B)], substituted ''pharmaceutically'' for ''pharmaceuutically''.

1997—Subsec. (g)(1)(B)(i)(III), (IV). Pub. L. 105–33, §4756, added subcl. (III) and redesignated former subcl. (III) as (IV).

Subsec. (j)(1). Pub. L. 105–33, §4701(b)(2)(A)(x), substituted ''health maintenance organizations, including medicaid managed care organizations'' for ''* * * Health Maintenance Organizations, including those organizations''.

1993—Subsec. (b)(1)(A). Pub. L. 103–66, §13602(a)(2)(A)(i)(II), which directed amendment of subpar. (A) by substituting ''dispensed after December 31, 1990, for which payment was made under the State plan for such period'' for ''dispensed under the plan during the quarter (or other period as the Secretary may specify)'', was executed by making the substitution for ''dispensed under the plan during the quarter (or such other period as the Secretary may specify)'' to reflect the probable intent of Congress.

Pub. L. 103–66, §13602(a)(2)(A)(i)(I), substituted ''for a rebate period'' for ''each calendar quarter (or periodically in accordance with a schedule specified by the Secretary)''.

Subsec. (b)(2)(A). Pub. L. 103–66, §13602(a)(2)(A)(ii), substituted ''each rebate period'' for ''each calendar quarter'' and ''units of each dosage form and strength and package size'' for ''dosage units'', inserted ''after December 31, 1990, for which payment was made'' after ''dispensed'', and substituted ''during the period'' for ''during the quarter''.

Subsec. (b)(3)(A)(i). Pub. L. 103–66, §13602(a)(2)(A)(iii), substituted ''rebate period under the agreement'' for ''quarter'' in two places.

Subsec. (c). Pub. L. 103–66, §13602(a)(1), added subsec. (c) and struck out former subsec. (c) which related to determination of amount of rebate for certain drugs.

Pub. L. 103–18 substituted ''such drug, except that for the calendar quarter beginning after September 30, 1992, and before January 1, 1993, the amount of the rebate may not exceed 50 percent of such average manufacturer price;'' for ''such drug;'' in par. (1)(B)(ii)(II).

Subsecs. (d) to (f). Pub. L. 103–66, §13602(a)(1), added subsecs. (d) and (e), struck out former subsecs. (d) consisting of pars. (1) to (8) relating to limitations on coverage of drugs, (e) relating to denial of Federal financial participation in certain cases, and (f)(1) relating to reductions in pharmacy reimbursement limits, and struck out par. designation for former par. (2) of subsec. (f) without supplying a new designation. The text of former subsec. (f)(2) is now the last par. of subsec. (e).

Subsec. (k)(1). Pub. L. 103–66, §13602(a)(2)(B)(i), substituted ''rebate period'' for ''calendar quarter'' and inserted before period at end '', after deducting customary prompt pay discounts''.

Subsec. (k)(3). Pub. L. 103–66, §13602(a)(2)(B)(ii)(III), in concluding provisions, substituted ''for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used'' for ''which is used'' and inserted at end ''Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection

(c)(1)(C) of this section) for such drug, biological product, or insulin.''

Subsec. (k)(3)(E). Pub. L. 103–66, § 13602(a)(2)(B)(ii)(I), struck out ''* * * *emergency room visits'' after ''services''.

Subsec. (k)(3)(F). Pub. L. 103–66, § 13602(a)(2)(B)(ii)(II), which directed amendment of subpar. (F) by substituting ''services and services provided by an intermediate care facility for the mentally retarded'' for ''services'', was executed by making the substitution for ''sevices'' to reflect the probable intent of Congress because the word ''services'' did not appear.

Subsec. (k)(6). Pub. L. 103–66, § 13602(a)(2)(B)(iii), substituted ''or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.'' for '', which appears in peer-reviewed medical literature or which is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information.''

Subsec. (k)(7)(A)(i). Pub. L. 103–66, § 13602(a)(2)(B)(iv), substituted ''rebate period'' for ''calendar quarter'' in introductory provisions.

Subsec. (k)(8), (9). Pub. L. 103–66, § 13602(a)(2)(B)(v), added par. (8) and redesignated former par. (8) as (9).

1992—Subsec. (a)(1). Pub. L. 102–585, § 601(b)(1), substituted ''manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6)'' for ''manufacturer)''.

Subsec. (a)(5), (6). Pub. L. 102–585, § 601(b)(2), added pars. (5) and (6).

Subsec. (b)(3)(D). Pub. L. 102–585, § 601(b)(3), substituted ''this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section'' for ''this paragraph'', ''Secretary or the Secretary of Veterans Affairs'' for ''Secretary'', and ''except—'' and cls. (i) to (iii) for ''except as the Secretary determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.''

Subsec. (b)(4)(B)(ii). Pub. L. 102–585, § 601(b)(4)(i), (ii), substituted ''the calendar quarter beginning at least 60 days'' for ''such period'' and ''the manufacturer provides notice to the Secretary.'' for ''of the notice as the Secretary may provide (but not beyond the term of the agreement).''

Subsec. (b)(4)(B)(iv), (v). Pub. L. 102–585, § 601(b)(4)(iii), added cls. (iv) and (v).

Subsec. (c)(1)(B)(i). Pub. L. 102–585, § 601(c)(1), which directed the substitution of ''October 1, 1992,'' for ''January 1, 1993,'', was executed by making the substitution in introductory provisions and in subcl. (II), to reflect the probable intent of Congress.

Subsec. (c)(1)(B)(ii) to (v). Pub. L. 102–585, § 601(c)(2), (3), added cls. (ii) to (v) and struck out former cl. (ii) which read as follows: ''for quarters (or other periods) beginning after December 31, 1992, the greater of—

''(I) the difference between the average manufacturer price for a drug and 85 percent of such price, or

''(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug.''

Subsec. (c)(1)(C). Pub. L. 102–585, § 601(a), substituted ''(excluding any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section, any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under a State pharmaceutical assistance program, and excluding'' for ''(excluding''.

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title IV, § 405(c)(2)(A), Dec. 20, 2006, 120 Stat. 2999, provided that the amendment made by section 405(c)(2)(A) is effective as if included in the enactment of the Deficit Reduction Act of 2005 (Public Law 109–171).

Pub. L. 109–171, title VI, § 6001(f)(3), Feb. 8, 2006, 120 Stat. 58, provided that: ''The amendments made by this subsection [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Feb. 8, 2006].''

Pub. L. 109–171, title VI, § 6001(g), Feb. 8, 2006, 120 Stat. 58, provided that: ''Except as otherwise provided, the amendments made by this section [amending this section and section 1395x of this title] shall take effect on January 1, 2007, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.''

Pub. L. 109–171, title VI, § 6003(c), Feb. 8, 2006, 120 Stat. 61, provided that: ''The amendments made by this section [amending this section] take effect on January 1, 2007.''

Pub. L. 109–171, title VI, § 6004(b), Feb. 8, 2006, 120 Stat. 61, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to drugs purchased on or after the date of the enactment of this Act [Feb. 8, 2006].''

EFFECTIVE DATE OF 2005 AMENDMENT

Amendment by Pub. L. 109–91 applicable to drugs dispensed on or after Jan. 1, 2006, see section 104(d) of Pub. L. 109–91, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title I, § 103(e)(2), Dec. 8, 2003, 117 Stat. 2160, provided that: ''Section 1927(c)(1)(C)(i)(VI) of the Social Security Act [subsec. (c)(1)(C)(i)(VI) of this section], as added by paragraph (1), shall apply to prices charged for drugs dispensed on or after January 1, 2006.''

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, § 1000(a)(6) [title VI, § 606(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–396, provided that: ''The amendment made by subsection (a) [amending this section] applies to agreements entered into on or after the date of enactment of this Act [Nov. 29, 1999].''

Amendment by section 1000(a)(6) [title VI, § 608(u)] of Pub. L. 106–113 effective Nov. 29, 1999, see section 1000(a)(6) [title VI, § 608(bb)] of Pub. L. 106–113, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–33 effective Aug. 5, 1997, and applicable to contracts entered into or renewed on or after Oct. 1, 1997, see section 4710 of Pub. L. 105–33, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 1993 AMENDMENTS

Section 13602(d) of Pub. L. 103–66 provided that:

''(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 1396a and 1396b of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508].

''(2) The amendment made by subsection (a)(1) [amending this section] (insofar as such subsection amends section 1927(d) of the Social Security Act [subsec. (d) of this section]) and the amendment made by subsection (c) [amending section 1396a of this title] shall apply to calendar quarters beginning on or after October 1, 1993, without regard to whether or not regulations to carry out such amendments have been promulgated by such date.''

Section 2(b) of Pub. L. 103–18 provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment

of section 601(c) of the Veterans Health Care Act of 1992 [Pub. L. 102–585].''

EFFECTIVE DATE OF 1992 AMENDMENT

Section 601(e) of Pub. L. 102–585 provided that: ''The amendments made by this section [amending this section] shall apply with respect to payments to State plans under title XIX of the Social Security Act [this subchapter] for calendar quarters (or periods) beginning on or after January 1, 1993 (without regard to whether or not regulations to carry out such amendments have been promulgated by such date).''

REGULATIONS

Pub. L. 109–171, title VI, §6001(c)(3), Feb. 8, 2006, 120 Stat. 55, provided that:

''(A) INSPECTOR GENERAL RECOMMENDATIONS.—Not later than June 1, 2006, the Inspector General of the Department of Health and Human Services shall—

''(i) review the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act [this section], as amended by this section; and

''(ii) shall submit to the Secretary of Health and Human Services and Congress such recommendations for changes in such requirements or manner as the Inspector General determines to be appropriate.

''(B) DEADLINE FOR PROMULGATION.—Not later than July 1, 2007, the Secretary of Health and Human Services shall promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined under section 1927 of the Social Security Act, taking into consideration the recommendations submitted to the Secretary in accordance with subparagraph (A)(ii).''

PHARMACY REIMBURSEMENT UNDER MEDICAID

Pub. L. 110–275, title II, §203, July 15, 2008, 122 Stat. 2592, provided that:

''(a) DELAY IN APPLICATION OF NEW PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS UNDER MEDICAID.—Notwithstanding paragraphs (4) and (5) of subsection (e) of section 1927 of the Social Security Act (42 U.S.C. 1396r–8) or part 447 of title 42, Code of Federal Regulations, as published on July 17, 2007 (72 Federal Register 39142)—

''(1) the specific upper limit under section 447.332 of title 42, Code of Federal Regulations (as in effect on December 31, 2006) applicable to payments made by a State for multiple source drugs under a State Medicaid plan shall continue to apply through September 30, 2009, for purposes of the availability of Federal financial participation for such payments; and

''(2) the Secretary of Health and Human Services shall not, prior to October 1, 2009, finalize, implement, enforce, or otherwise take any action (through promulgation of regulation, issuance of regulatory guidance, use of Federal payment audit procedures, or other administrative action, policy, or practice, including a Medical Assistance Manual transmittal or letter to State Medicaid directors) to impose the specific upper limit established under section 447.514(b) of title 42, Code of Federal Regulations as published on July 17, 2007 (72 Federal Register 39142).

''(b) TEMPORARY SUSPENSION OF UPDATED PUBLICLY AVAILABLE AMP DATA.—Notwithstanding clause (v) of section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)), the Secretary of Health and Human Services shall not, prior to October 1, 2009, make publicly available any AMP disclosed to the Secretary.

''(c) DEFINITIONS.—In this subsection:

''(1) The term 'multiple source drug' has the meaning given that term in section 1927(k)(7)(A)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(7)(A)(i)).

''(2) The term 'AMP' has the meaning given 'average manufacturer price' in section 1927(k)(1) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)) and 'AMP' in section 447.504(a) of title 42, Code of Federal Regulations as published on July 17, 2007 (72 Federal Register 39142).''

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under subchapter XVIII of this chapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

REPORTS ON BEST PRICE CHANGES AND PAYMENT OF REBATES

Section 601(d) of Pub. L. 102–585 provided that not later than 90 days after the expiration of each calendar quarter beginning on or after Oct. 1, 1992, and ending on or before Dec. 31, 1995, Secretary of Health and Human Services was to submit to Congress a report containing information as to percentage of single source drugs whose best price either increased, decreased, or stayed the same in comparison to best price during previous calendar quarter, median and mean percentage increase or decrease of such price, and, with respect to drugs for which manufacturers were required to pay rebates under subsec. (c) of this section, Secretary's best estimate, on State-by-State and national aggregate basis, of total amount of rebates paid under subsec. (c) of this section and percentages of such total amounts attributable to rebates paid under pars. (1) to (3) of subsec. (c) of this section, limited consideration to drugs which are considered significant expenditures under medicaid program, and contained requirements for initial report.

DEMONSTRATION PROJECTS TO EVALUATE EFFICIENCY AND COST-EFFECTIVENESS OF PROSPECTIVE DRUG UTILIZATION REVIEW

Section 4401(c) of title IV of Pub. L. 101–508 directed Secretary of Health and Human Services to establish statewide demonstration projects to evaluate efficiency and cost-effectiveness of prospective drug utilization review and to evaluate impact on quality of care and cost-effectiveness of paying pharmacists under this subchapter whether or not drugs were dispensed for drug use review services, with two reports to be submitted to Congress, the first not later than Jan. 1, 1994, and the second not later than Jan. 1, 1995.

STUDY OF DRUG PURCHASING AND BILLING PRACTICES IN HEALTH CARE INDUSTRY; REPORT

Section 4401(d) of title IV of Pub. L. 101–508, as amended by Pub. L. 104–316, title I, §122(i), Oct. 19, 1996, 110 Stat. 3837, provided for various studies and reports as follows: (1) directed Comptroller General to conduct study of drug purchasing and billing activities of various health care systems, and to submit report to Secretary of Health and Human Services and to Congress by not later than May 1, 1991; (2) directed Comptroller General to submit to Secretary and Congress report on changes in prices charged by manufacturers for prescription drugs to Department of Veterans Affairs, other Federal programs, hospital pharmacies, and other purchasing groups and managed care plans; (3) directed Secretary, acting in consultation with Comptroller General, to study prior approval procedures utilized by State medical assistance programs conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; (4) directed Secretary to conduct study on adequacy of current reimbursement

rates to pharmacists under each State medical assistance program conducted under this subchapter, and to submit report to Congress by not later than Dec. 31, 1991; and (5) directed Secretary to undertake study of relationship between State medical assistance plans and Federal and State acquisition and reimbursement policies for vaccines and accessibility of vaccinations and immunization to children, and to report to Congress not later than one year after Nov. 5, 1990.

§ 1396s. Program for distribution of pediatric vaccines

(a) Establishment of program

(1) In general

In order to meet the requirement of section 1396a(a)(62) of this title, each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section, under which—

(A) each vaccine-eligible child (as defined in subsection (b) of this section), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8) of this section) from a program-registered provider (as defined in subsection (c) of this section) on or after October 1, 1994, is entitled to receive the immunization without charge for the cost of such vaccine; and

(B)(i) each program-registered provider who administers such a pediatric vaccine to a vaccine-eligible child on or after such date is entitled to receive such vaccine under the program without charge either for the vaccine or its delivery to the provider, and (ii) no vaccine is distributed under the program to a provider unless the provider is a program-registered provider.

(2) Delivery of sufficient quantities of pediatric vaccines to immunize federally vaccine-eligible children

(A) In general

The Secretary shall provide under subsection (d) of this section for the purchase and delivery on behalf of each State meeting the requirement of section 1396a(a)(62) of this title (or, with respect to vaccines administered by an Indian tribe or tribal organization to Indian children, directly to the tribe or organization), without charge to the State, of such quantities of qualified pediatric vaccines as may be necessary for the administration of such vaccines to all federally vaccine-eligible children in the State on or after October 1, 1994. This paragraph constitutes budget authority in advance of appropriations Acts, and represents the obligation of the Federal Government to provide for the purchase and delivery to States of the vaccines (or payment under subparagraph (C)) in accordance with this paragraph.

(B) Special rules where vaccine is unavailable

To the extent that a sufficient quantity of a vaccine is not available for purchase or delivery under subsection (d) of this section, the Secretary shall provide for the purchase and delivery of the available vaccine in accordance with priorities established by the Secretary, with priority given to federally vaccine-eligible children unless the Secretary finds there are other public health considerations.

(C) Special rules where State is a manufacturer

(i) Payments in lieu of vaccines

In the case of a State that manufactures a pediatric vaccine the Secretary, instead of providing the vaccine on behalf of a State under subparagraph (A), shall provide to the State an amount equal to the value of the quantity of such vaccine that otherwise would have been delivered on behalf of the State under such subparagraph, but only if the State agrees that such payments will only be used for purposes relating to pediatric immunizations.

(ii) Determination of value

In determining the amount to pay a State under clause (i) with respect to a pediatric vaccine, the value of the quantity of vaccine shall be determined on the basis of the price in effect for the qualified pediatric vaccine under contracts under subsection (d) of this section. If more than 1 such contract is in effect, the Secretary shall determine such value on the basis of the average of the prices under the contracts, after weighting each such price in relation to the quantity of vaccine under the contract involved.

(b) Vaccine-eligible children

For purposes of this section:

(1) In general

The term ''vaccine-eligible child'' means a child who is a federally vaccine-eligible child (as defined in paragraph (2)) or a State vaccine-eligible child (as defined in paragraph (3)).

(2) Federally vaccine-eligible child

(A) In general

The term ''federally vaccine-eligible child'' means any of the following children:

(i) A medicaid-eligible child.

(ii) A child who is not insured.

(iii) A child who (I) is administered a qualified pediatric vaccine by a federally-qualified health center (as defined in section 1396d(*l*)(2)(B) of this title) or a rural health clinic (as defined in section 1396d(*l*)(1) of this title), and (II) is not insured with respect to the vaccine.

(iv) A child who is an Indian (as defined in subsection (h)(3) of this section).

(B) Definitions

In subparagraph (A):

(i) The term ''medicaid-eligible'' means, with respect to a child, a child who is entitled to medical assistance under a state[1] plan approved under this subchapter.

(ii) The term ''insured'' means, with respect to a child—

[1] So in original. Probably should be capitalized.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1678–P]

RIN 0938–AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems and certain provisions under the 21st Century Cures Act (Pub. L. 114–255). In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES: *Comment period:* To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 11, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth Daniel at 410–786–0237 or via email *Elisabeth.Daniel1@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia at 410–786–7236 or via email *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur at 410–786–8819 or via email *Vinitha.Meyyur@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters at 410–786–9732 or via email *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga at 410–786–4142 or via email *Scott.Talaga@cms.hhs.gov*.

Care Management Services, contact Scott Talaga at 410–786–4142 or via email *Scott.Talaga@cms.hhs.gov*.

CPT Codes, contact Marjorie Baldo at 410–786–4617 or via email *Marjorie.Baldo@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver at 410–786–6719 or via email *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson at 410–786–1159 or via email *Twi.Jackson@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Lela Strong at 410–786–3213 or via email *Lela.Strong@cms.hhs.gov*.

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Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur at 410–786–8819 or via email *Vinitha.Meyyur@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at 410–786–1159 or via email *Twi.Jackson@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Lela Strong at 410–786–3213 or via email *Lela.Strong@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga at 410–786–4142 or via email *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson at 410–786–1159 or via email *Twi.Jackson@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga at 410–786–4142 or via email *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang

specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We are seeking public comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it would take approximately 6.4 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $673 (6.4 hours x $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $1,708,074 ($673 x 2,538 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Proposed Rule

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2018 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2018 with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1678–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 38 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the proposed individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

We are soliciting public comment and information about the anticipated effects of the proposed changes included in this proposed rule on providers and our methodology for estimating them. Any public comments that we receive will be addressed in the applicable sections of the final rule with comment period that discuss the specific policies.

(2) Estimated Effects of Proposed OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7. of this proposed rule, we discuss our proposal to reduce the payment for nonpass-through, separately payable drugs purchased by 340B-participating hospitals through the 340B drug pricing program. Specifically, we are proposing to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through status and vaccines, at the average sales price (ASP) minus 22.5 percent instead of ASP+6 percent.

We recognize that it is difficult to determine precisely what the impact on Medicare spending would be because OPPS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs covered under the 340B program is not publicly available. Accordingly, for purposes of estimating the impact, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B drug pricing program were purchased at a discounted price under the 340B program. We assumed that all governmental-owned, cancer, and children's hospitals, as well as those hospitals with a DSH percentage greater than 11.75 percent, sole community hospitals with a DSH percentage greater than 8 percent, and rural referral centers with a DSH percentage greater than 8 percent, all participated in the 340B program. We did not assume changes in the quantity of 340B purchased drugs provided (thereby affecting unit volume) or changes in the number of hospitals participating in the 340B program that may occur due to the proposed payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this proposed rule, we note that each hospital has the ability to calculate how this proposal would change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program would know that its Medicare payments for drugs would be unaffected by this proposal; whereas each hospital participating in the 340B program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, an affected hospital is able to estimate the difference in payment that it would receive if Medicare were to pay ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using CY 2016 claims data for the applicable separately payable drugs and biologicals, excluding those on pass-through status and vaccines, billed by hospitals eligible to participate in the 340B program, we estimate that OPPS payments for separately payable drugs, including beneficiary copayment, could decrease by as much as $900 million under this proposal. Because we are proposing to implement this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B drug pricing program would increase payment rates (and by extension, beneficiary coinsurance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 416, and 419

[CMS–1678–FC]

RIN 0938–AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2018 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2018, unless otherwise noted.

Comment period: To be assured consideration, comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB with the comment indicator ''NI'' and on other areas specified throughout this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 31, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1678–FC when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1678–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

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a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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Care Management Services, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

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Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov* or at 410–786–1816 or Elisabeth Daniel via email *Elisabeth.Daniel1@cms.hhs.gov* or at 410–786–0237.

(HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2018. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

• *OPPS Update:* For CY 2018, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.35 percent. This increase factor is based on the hospital inpatient market basket percentage increase of 2.7 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.6 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2018 is approximately $70 billion, an increase of approximately $5.8 billion compared to estimated CY 2017 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *High Cost/Low Cost Threshold for Packaged Skin Substitutes:* As we did for CY 2017, we are assigning skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, for CY 2018, we are establishing that a skin substitute product that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, is assigned to the high cost group for CY 2018. The goal of our policy is to maintain similar levels of payment for skin substitute products for CY 2018 while we study our current skin substitute payment methodology to determine whether refinements to our existing methodologies may be warranted.

• *Supervision of Hospital Outpatient Therapeutic Services:* In the CY 2009 and CY 2010 OPPS/ASC proposed rules and final rules with comment period, we clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, CAHs, and in provider-based departments (PBDs) of hospitals, as set forth in the CY 2000 OPPS final rule with comment period. For several years, there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2016. In this final rule with comment period, as we proposed, we are reinstating the nonenforcement policy for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals having 100 or fewer beds and reinstating our enforcement instruction for CY 2018 and CY 2019.

• *340B Drug Pricing:* We are changing our current Medicare Part B drug payment methodology for 340B hospitals that we believe will better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. These changes will lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program. For CY 2018, we are exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. In addition, in this final rule with comment period, we are establishing two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program.

• *Device Pass-Through Payment Applications:* For CY 2018, we evaluated five devices for eligibility to receive pass through payments and sought public comments in the CY 2018 proposed rule on whether each of these items meet the criteria for device pass-through payment status. None of the applications were approved for device pass-through payments for CY 2018.

• *Rural Adjustment:* We are continuing the adjustment of 7.1 percent to the OPPS payments to certain rural SCHs, including essential access community hospitals (EACHs). This adjustment will apply to all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost.

• *Cancer Hospital Payment Adjustment:* For CY 2018, we are continuing to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, beginning CY 2018, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a target PCR of 0.88 will be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *Changes to the Inpatient Only List:* For CY 2018, we are finalizing our proposal to remove total knee arthroplasty (TKA) from the inpatient only list. In addition, we are precluding the Recovery Audit Contractors from reviewing TKA procedures for ''patient status'' (that is, site of service) for a period of 2 years. We note that we will monitor changes in site of service to determine whether changes may be necessary to certain CMS Innovation Center models. In addition, we are removing five other procedures from the inpatient only list and adding one procedure to the list.

• *Comprehensive APCs:* For CY 2018, we did not propose to create any new C–APCs or make any extensive changes to the already established methodology used for C–APCs. There will be a total

physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2017 updated furnishing fee was $0.209 per unit.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the MPFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

Comment: Commenters' supported CMS' proposal to continue to pay for a blood clotting factor furnishing fee in the hospital outpatient department.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS Web site.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2018 OPPS/ASC proposed rule (82 FR 33631), for CY 2018, we proposed to continue to use the same payment policy as in CY 2017 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data was listed in Addendum B to the proposed rule, which is available via the Internet on the CMS Web site.

Comment: One commenter, the manufacturer of Mylotarg®, requested that CMS change the dose descriptor for HCPCS code J9300 from ''Injection, gemtuzumab ozogamicin, 5 mg'' to ''Injection, gemtuzumab ozogamicin, 0.1 mg,'' to accommodate the new 4.5 mg vial size for Mylotarg®. The commenter noted that HCPCS code J9300 was inactive for a period of time because the prior version of gemtuzumab ozogamicin was removed from the market. As such, HCPCS code J9300 is assigned status indicator ''E2 (items and services for which pricing information and claims data are not available).'' The commenter also requested that CMS change the status indicator from ''E2'' to a payable status indicator.

Response: This comment is outside of the scope of the proposed rule. Requests for changes to Level II Alphanumeric HCPCS codes should be submitted to the CMS HCPCS Workgroup using CMS' standard procedures. Information on the Level II HCPCS code process is available via the Internet on the CMS Web site, which is publicly available at: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSCODINGPROCESS.html.*

After consideration of the public comments we received, we are finalizing our CY 2018 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2018 if pricing information becomes available. The CY 2018 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the Internet on the CMS Web site.

7. Alternative Payment Methodology for Drugs Purchased Under the 340B Program

a. Background

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.[18]

The 340B statute defines which health care providers are eligible to participate in the program (''covered entities''). In addition to Federal health care grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent. However, under Public Law 111–148, section 7101 expanded eligibility to critical access hospitals (CAHs), children's hospitals with a DSH adjustment greater than 11.75 percent, sole community hospitals (SCHs) with a DSH adjustment percentage of 8.0 percent or higher, rural referral centers (RRCs) with a DSH adjustment percentage of 8.0 percent or higher, and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. In accordance with section 340B(a)(4)(L)(i) of the Public Health Service Act, all participating hospital types must also meet other criteria.

HRSA calculates the ceiling price for each covered outpatient drug. The ceiling price is the drug's average manufacturer price (AMP) minus the unit rebate amount (URA), which is a

[18] The House report that accompanied the authorizing legislation for the 340B Program stated: ''In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'' (H.R. Rept. No. 102–384(II), at 12 (1992)).

statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug.[19] The ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug. However, covered entities also have the option to participate in HRSA's Prime Vendor Program (PVP), under which the prime vendor can negotiate even deeper discounts (known as ''subceiling prices'') on some covered outpatient drugs. By the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price.[20]

As we discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33632 and 33633), several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost.[21] [22] [23] Links to the full reports referenced in this section can be found in the cited footnotes.

In its May 2015 Report to Congress, MedPAC analyzed Medicare hospital outpatient claims (excluding CAHs) along with information from HRSA on which hospitals participate in the 340B Program. MedPAC included data on all separately payable drugs under the OPPS except for vaccines and orphan drugs provided by freestanding cancer hospitals, RRCs, and SCHs. To estimate costs that 340B hospitals incur to acquire drugs covered under the OPPS, MedPAC generally used the formula for calculating the 340B ceiling price: (AMP)—unit rebate amount (URA) × drug package size. The URA is determined by law and depends upon whether a drug is classified as single source, innovator multiple source, non-innovator multiple source, a clotting factor drug, or an exclusively pediatric drug. CMS provides this URA information to States as a courtesy. However, drug manufacturers remain responsible for correctly calculating the URA for their covered outpatient drugs. More information on the URA calculation and the Medicaid Drug Rebate Program may be found on the Web site at: *https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html.*

Because MedPAC did not have access to AMP data, it used each drug's ASP as a proxy for AMP. MedPAC noted that ASP is typically slightly lower than AMP. The AMP is defined under section 1927(k)(1) of the Act as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts. Manufacturers participating in Medicaid are required to report AMP data quarterly to the Secretary, and these prices are confidential. As described under section 1847A of the Act, the ASP is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge and 340B discounts.

In addition, MedPAC noted that, due to data limitations, its estimates of ceiling prices are conservative and likely higher (possibly much higher) than actual ceiling prices. Further details on the methodology used to calculate the average minimum discount for separately payable drugs can be found in Appendix A of MedPAC's May 2015 Report to Congress. In this report, MedPAC estimated that, on average, hospitals in the 340B Program ''receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS].''

In its March 2016 Report to Congress (page 79), MedPAC noted that another report, which MedPAC attributed to the Office of the Inspector General (OIG), recently estimated that discounts across all 340B providers (hospitals and certain clinics) average 33.6 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs. According to the U.S. Government Accountability Office (GAO) report, the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, participation in the PVP often results in a covered entity paying a subceiling price on some covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price) (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification). Participation in the PVP is voluntary and free.

As noted in the CY 2018 OPPS/ASC proposed rule, with respect to chemotherapy drugs and drug administration services, MedPAC examined Medicare Part B spending for 340B and non-340B hospitals for a 5-year period from 2008 to 2012 and found that ''Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period'' (MedPAC May 2015 Report to Congress, page 14). This is just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs.

Further, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals.'' According to the GAO report, this indicates that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status (GAO Report 15–442, page 20).

Under the OPPS, all hospitals (other than CAHs, which are paid based on 101 percent of reasonable costs as required by section 1834(g) of the Act) are currently paid the same rate for separately payable drugs (ASP+6

[19] 42 U.S.C. 256b(a)(1–2). Occasionally, a drug's URA is equal to its AMP, resulting in a 340B ceiling price of $0. In these instances, HRSA has advised manufacturers to charge covered entities $0.01 per unit.

[20] Department of Health and Human Services. 2017. Fiscal Year 2018 Health Resources and Services Administration justification of estimates for appropriations committees. Washington, DC: HHS. Available at: *https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf.*

[21] Office of Inspector General. ''Part B Payment for 340B Purchased Drugs. OEI–12–14–00030''. November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[22] Medicare Payment Advisory Commission. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015. Available at: *http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.*

[23] Government Accountability Office. ''Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO–15–442''. June 2015. Available at: *https://www.gao.gov/assets/680/670676.pdf.*

percent), regardless of whether the hospital purchased the drug at a discount through the 340B Program. Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug). Based on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the OIG found that, for 35 drugs, the ''difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone . . . was greater than the amount a covered entity spent to acquire the drug'' (OIG November 2015, Report OEI–12–14–00030, page 9).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68655), we requested comments regarding the drug costs of hospitals that participate in the 340B Program and whether we should consider an alternative drug payment methodology for participating 340B hospitals. As noted above, in the time since that comment solicitation, access to the 340B Program was expanded under section 7101 of Public Law 111–148, which amended section 340B(a)(4) of the Public Health Service Act to expand the types of covered entities eligible to participate in the 340B Program. It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013.[24] In addition, the number of hospitals participating in the program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014 (MedPAC May 2015 Report to Congress). In its November 2015 report entitled ''Part B Payments for 340B-Purchased Drugs,'' the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013 (OEI–12–14–00030, page 8). Given the growth in the number of providers participating in the 340B Program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we stated in the CY 2018 OPPS/ASC proposed rule that we believe it is timely to reexamine the appropriateness of continuing to apply the current OPPS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B Program at significantly discounted rates.

MedPAC and OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. In its March 2016 Report to Congress, MedPAC recommended a legislative proposal related to payment for Part B drugs furnished by 340B hospitals under which Medicare would reduce payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the ASP and direct the program savings from reducing Part B drug payment rates to the Medicare funded uncompensated care pool.[25] In its November 2015 report, the OIG described three options under which both the Medicare program and Medicare beneficiaries would be able to share in the program savings realized by hospitals and other covered entities that participate in the 340B Program (OEI–12–14–00030, pages 11–12). These options included: (1) Paying ASP with no additional add-on percentage; (2) paying ASP minus 14.4 percent; and (3) making payment based on the 340B ceiling price plus 6 percent of ASP for each 340B purchased drug (OEI–12–14–00030, page 11). Analysis in several of these reports notes limitations in estimating 340B-purchased drugs' acquisition costs; the inability to identify which drugs were purchased through the 340B Program within Medicare claims data was one of those limitations.

b. OPPS Payment Rate for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33633 through 33634), we proposed changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Medicare expenditures on Part B drugs have been rising and are projected to continue to rise faster than overall health spending, thereby increasing this sector's share of health care spending due to a number of underlying factors such as new higher price drugs and price increases for existing drugs.[26] [27] While we recognize the intent of the 340B Program, we believe it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs. We believe that any payment changes we adopt should be limited to separately payable drugs under the OPPS, with some additional exclusions. As a point of further clarity, CAHs are not included in this 340B policy change because they are paid under section 1834(g) of the Act. As stated in the CY 2018 OPPS/ASC proposed rule, these exclusions are for: (1) Drugs on pass-through payment status, which are required to be paid based on the ASP methodology, and (2) vaccines, which are excluded from the 340B Program. In addition, we solicited public comments on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

Data limitations inhibit our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the proposed rule that we intended to provide further details about this modifier in this CY

[24] U.S. Department of Health and Human Services, HRSA FY 2015 Budget Justification, p. 342.

[25] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at: *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

[26] Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Medicare Part B Drugs: Pricing and Incentives. 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

[27] Department of Health and Human Services: Office of the Assistant Secretary for Planning and Evaluation. Issue Brief: Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: *https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf.*

2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program.

A summary of public comments received and our responses pertaining to the modifier are included later in this section. As described in detail later in this section, we are implementing the modifier such that it is required for drugs that were acquired under the 340B Program instead of requiring its use on drugs that were *not* acquired under the 340B Program. In addition, we are establishing an informational modifier for use by certain providers who will be excepted from the 340B payment reduction.

Further, we note that the confidentiality of ceiling and subceiling prices limits our ability to precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug. We recognize that each separately payable OPPS drug will have a different ceiling price (or subceiling price when applicable). Accordingly, we stated in the proposed rule that we believe using an average discounted price was appropriate for our proposal. Therefore, for CY 2018, we proposed to apply an average discounted price of 22.5 percent of the ASP for nonpass-through separately payable drugs purchased under the 340B Program, as estimated by MedPAC (MedPAC's May 2015 Report to Congress, page 7).

In the near-term, we believe that the estimated average minimum discount MedPAC calculated—22.5 percent of the ASP—adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate and noted that the analysis is spelled out in detail and can be replicated by interested parties. As MedPAC noted, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent of the ASP. As GAO mentioned, discounts under the 340B Program range from 20 to 50 percent of the ASP (GAO–11–836, page 2). We believe that such reduced payment would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary. We do not have hospital acquisition cost data for 340B drugs and, therefore, proposed to continue to pay for these drugs under our authority at section 1833(t)(14)(A)(iii)(II) of the Act at ASP, and then to adjust that amount by applying a reduction of 22.5 percent, which, as explained throughout this section, is the adjustment we believe is necessary for drugs acquired under the 340B Program.

Specifically, in the CY 2018 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. However, we proposed to exercise the Secretary's authority to adjust the applicable payment rate as necessary and, for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program, we proposed to adjust the rate to ASP minus 22.5 percent, which we believe better represents the average acquisition cost for these drugs and biologicals.

As indicated earlier, because ceiling prices are confidential, we are unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug. We believe that the MedPAC analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPPS receive. In addition, we believe that using an average discount to set payment rates for OPPS separately payable drugs would achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs, and (2) protecting the confidential nature of discounts applied to a specific drug. Moreover, we do not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug under the 340B Program is much lower than the ASP for the drug.

We note that MedPAC excluded vaccines from its analysis because vaccines are not covered under the 340B Program, but it did not exclude drugs with pass-through payment status. Further, because data used to calculate ceiling prices are not publicly available, MedPAC instead estimated ''the lower bound of the average discount received by 340B hospitals for drugs paid under the [OPPS]'' (MedPAC May 2015 Report to Congress, page 6). Accordingly, it is likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis. In the proposed rule, we encouraged the public to analyze the analysis presented in Appendix A of MedPAC's May 2015 Report to Congress.

As noted earlier, we believe that the discount amount of 22.5 percent below the ASP reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program, and in many cases, the average discount may be higher for some covered outpatient drugs due to hospital participation in the PVP, substitution of ASP (which includes additional rebates) for AMP, and that drugs with pass-through payment status were included rather than excluded from the MedPAC analysis. We believe that a payment rate of ASP+6 percent does not sufficiently recognize the significantly lower acquisition costs of such drugs incurred by a 340B-participating hospital. Accordingly, as noted earlier, we proposed to reduce payment for separately payable drugs, excluding drugs on pass-through payment status and vaccines, that were acquired under the 340B Program by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier mentioned in the proposed rule and discussed further in this final rule with comment period. (As detailed later in this section, we are instead requiring hospitals to append the applicable modifier on the claim line with any drugs that were acquired under the 340B Program.)

Finally, as detailed in the impact analysis section (section XIX.A.5.a.2) of the proposed rule, we also proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program. In that section, we also solicited public comments on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018,

rather than simply increasing the conversion factor. In particular, we requested public comments on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. In addition, we requested public comments on whether savings associated with this proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act. More information on the impact estimate associated with this proposal was included in section XIX.A.5.a.2. of the proposed rule. A summary of the public comments received on the impact estimate, along with our responses to those comments and our estimate of this provision for this final rule with comment period, are included in section XVIII.A.5. of this final rule with comment period.

c. Summaries of Public Comments Received and Our Responses

(1) Overall Comments

Comment: Several commenters, including organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and several individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, and preserve patient access to community-based care.

One of these commenters stated that the proposals would reduce drug costs for seniors by an estimated $180 million a year; help to stop hospital ''abuses'' of the 340B program; and help reverse the ''perverse incentives'' that have driven the closure and consolidation of the nation's community cancer care system.

Another commenter, representing a large network of community-based oncology practices, noted that since 2008, 609 community cancer practices have been acquired or become affiliated with hospitals, with 75 percent of those community cancer practices acquired by 340B-participating hospitals. The commenter stated that the consolidation in oncology care has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more costly hospital outpatient setting.

One commenter, an organization representing community oncology practices, cited several issues that the proposal would help address, including that only a small minority of 340B participating hospitals are using the program to benefit patients in need; cancer patients in need are being denied care at 340B participating hospitals or placed on wait lists; and hospitals are making extreme profits on expensive cancer drugs and are consolidating the nation's cancer care system, reducing patient choice and access and shifting care away from the private, physician-owned community oncology clinics into the more expensive 340B hospital setting, which is increasing costs for Medicare and its beneficiaries. In addition, this commenter stated that the increasing scope and magnitude of required 340B discounts are increasing drug prices to record-breaking levels as manufacturers factor these discounts into pricing decisions. The commenter also cited a report that it recently released that suggests, and provides anecdotal evidence supporting, that some 340B hospitals offered little charity care and turned away some patients in need because those patients were uninsured.[28]

With respect to the magnitude of the proposed payment reduction of ASP minus 22.5 percent, one commenter noted that although the proposed decrease in payment may seem ''severe,'' ASP minus 22.5 percent is the minimum discount that hospitals in the 340B Program receive. The commenter further noted that, with 340B discounts on brand drugs approaching, and even exceeding, 50 percent, there is still substantial savings—on the order of 50 percent drug margins—for hospitals to use to provide direct and indirect patient benefits. The commenter also noted that this proposal would result in cost-sharing savings to Medicare beneficiaries, for whom drug cost is an important component of overall outpatient cancer care costs.

Some commenters urged HHS, specifically CMS and HRSA, to work with Congress to reform the 340B Program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the ''340B patient,'' which the commenter noted would require a legislative change.

Response: We thank the commenters for their support. As mentioned in the proposed rule, we share the commenters' concern that current Medicare payments for drugs acquired under the 340B Program are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We continue to believe that our proposal would better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs. Importantly, we continue to believe that Medicare beneficiaries should be able to share in the savings on drugs acquired through the 340B Program at a significant discount. We also appreciate the comments supporting the proposed payment amount for drugs acquired under the 340B Program of ASP minus 22.5 percent, which we believe, like several commenters, is an amount that allows hospitals to retain a profit on these drugs for use in the care of low-income and uninsured patients. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments.

As previously stated, CMS does not administer the 340B Program. Accordingly, feedback related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: Several commenters expressed concern with the rising cost of drugs and the impact on beneficiaries and taxpayers. These commenters offered varied opinions on whether the proposal would achieve CMS' goal of lowering drug prices and reducing beneficiary out-of-pocket costs. Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients. Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs, especially oncology drugs, CMS should not finalize the proposal.

One commenter, an individual who supported the proposal, stated that although the majority of patients with Medicare Part B coverage have supplemental coverage to pay their coinsurance, significant numbers do not have this additional protection. The commenter noted that, for a drug that is paid at $10,000 per month, the price reduction would save a beneficiary approximately $500 a month, which may be the difference between getting treatment and foregoing treatment due to financial reasons.

Another commenter, a large organization with many members who

[28] Community Oncology Alliance. Report: ''How Abuse of the 340B Program is Hurting Patients'' September 2017. Available at: *https://www.communityoncology.org/wp-content/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf.*

are Medicare beneficiaries, stated that the proposal would provide a measure of price relief to the 16 percent of Medicare beneficiaries without supplemental coverage. The commenter also expressed concern that the proposal would have serious health implications for beneficiaries in safety-net hospitals. The commenter urged HHS to develop proposals that will lower underlying drug prices, but did not provide any specific examples of such proposals. Another commenter stated that the cost of drugs is becoming unsustainable and applying the proposed policy is a decent ''baby step'' in controlling a situation that is ''grossly'' unfair to American taxpayers, especially when the development of new drugs is frequently funded to a large extent by taxpayers through Federal grants.

In addition, one commenter, a large organization representing its physician and medical student members, commented that it shares the Administration's interest in addressing the rising costs of drugs and biologicals. The commenter appreciated that the proposal would address a longstanding concern: That the current payment policy for Part B drugs creates strong incentives to move Medicare beneficiary care from lower cost sites of care (such as physician offices) to higher cost sites of care (such as hospital outpatient departments). The commenter noted that many smaller physician practices have had to refer cancer and other patients who need chemotherapy and other expensive drugs to the hospital outpatient setting because the ASP+6 percent payment does not always cover a physician's acquisition cost, thereby undermining continuity of care and creating burdens for frail and medically compromised patients.

This commenter also stated that, given the 340B Program's focus on low-income patients, it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs. Further, the commenter noted that it is essential that ''a bright line policy does not inadvertently deleteriously impact patient access in all sites of care.'' Finally, the commenter stated that, while the proposed policy alters the relative disparity between payments for some hospital outpatient departments and physician practices, it still does not address the persistent challenges physician practices face in obtaining payment that covers acquisition costs.

Response: We thank the commenters' for their feedback and share their concern about the high cost of drugs and their effect on Medicare beneficiaries. As discussed in detail later in this section, we are finalizing a change to the payment rate for certain Medicare Part B drugs purchased by hospitals through the 340B Program in order to lower the cost of drugs for seniors and ensure that they benefit from the discounts provided through the program. We look forward to working with Congress to provide HHS additional 340B programmatic flexibility, which could include tools to provide additional considerations for safety net hospitals, which play a critical role in serving our most vulnerable populations.

As a general matter, we note that, even though many beneficiaries have supplemental coverage, beneficiaries often pay a premium for such supplemental coverage and those plans make coinsurance payments for the beneficiary. Thus, to the extent Medicare would be lessening the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans to decrease or otherwise reflect these lower costs in the future, thereby lowering the amount that beneficiaries pay for supplemental plan coverage. Further, for those Medicare beneficiaries who do not have supplemental coverage at all or who have a supplemental plan that does not cover all of a beneficiary's cost-sharing obligation, the proposed policy would directly lower out-of-pocket spending for 340B-acquired drugs for those beneficiaries.

In addition, we note that in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 Drug Administration services and believe that these steps, taken together, may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

As previously stated, we believe that ASP minus 22.5 percent is a lower bound estimate of the average discount given to hospitals participating in the 340B Program. Accordingly, we disagree that this proposal represents a ''bright-line'' policy that would hinder safety-net hospitals' ability to treat patients.

While the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority, and we are committed to finding ways for Medicare payment policy not to incentivize use of overpriced drugs. With respect to Medicare Part B drug payment under the OPPS, we believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital by reducing their copayments. Further, to the extent that studies have found that 340B participating hospitals tend to use more high cost drugs, we believe that this proposal helps address the incentive for hospitals to utilize these drugs in this manner solely for financial reasons.

The expansion of 340B entities, the volume of 340B discounted drugs, and the affordability of drugs are outside the authority conferred by section 1833(t) of the Act (and, thus, are outside the scope of the proposed rule), and we see no reason to withdraw the proposal solely on account of these issues not being addressed by the proposal. Likewise, we note that the public comments on Medicare Part B drug payment in the physician office setting are also outside the scope of the proposed rule, and, therefore, are not addressed in this final rule with comment period.

Comment: Several commenters, including organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals, were generally opposed to the proposed changes and urged CMS to withdraw the proposal from consideration. As detailed further below, these commenters believed that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs, and contended that such change would effectively eviscerate the 340B Program. The commenters further noted that Medicare payment cuts of this magnitude would greatly ''undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program.''

These commenters urged that, rather than ''punitively targeting'' 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS instead redirect its efforts to halt the ''unchecked, unsustainable increases'' in the price of drugs.

Response: We do not believe that our proposed policy ''punitively'' targets safety-net hospitals. The current OPPS payment rate of ASP+6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout this section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive. We also have noted that 340B participation does not appear to be well-aligned with the provision of uncompensated care, as some commenters suggested. As stated earlier in this section, while the commenter's request that HHS develop proposals to lower underlying drug prices is outside the scope of the proposals made in the proposed rule, we note that lowering the price of pharmaceuticals is a top priority.

(2) Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. These comments are summarized into the broad categories below. For the reasons stated below, we disagree with these comments and believe that our proposal is within our statutory authority to promulgate.

• *Secretary's Authority To Calculate and Adjust 340B-Acquired Drug Payment Rates*

Comment: Commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act does not authorize CMS to ''calculate and adjust'' the payment rate in a manner that would ''eviscerate'' the 340B Program as it applies to 340B hospitals. Some commenters asserted that the plain and ordinary meaning of the terms ''calculate'' and ''adjust'' express a limited and circumscribed authority to set the payment rate. The commenters noted that the Oxford Dictionaries define ''calculate'' as ''determine (the amount or number of something) mathematically;'' likewise, to ''adjust'' is to ''alter or move (something) slightly in order to achieve the desired fit, appearance, or result.'' Consequently, the commenters asserted that section 1833(t)(14)(A)(iii)(II) of the Act restricts the agency to mathematically determining ''an appropriate, slight alteration.'' Further, they posited that the law does not convey the power to adopt what they referred to as a novel, sweeping change to the payment rate that is a significant numerical departure from the previous rate and that would result in a reduction in payment to 340B hospitals of at least $900 million, according to the agency's own estimates, or $1.65 billion, according to the commenter's estimates.

Another commenter stated that the Secretary's limited adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act does not ''extend so far as to gut'' what it referred to as an ''explicit statutory directive''. For example, the commenter referred the agency to *Pettibone Corp.* v. *United States,* 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute ''must not be confused with a power to rewrite'').

Some commenters, including an organization representing over 1,300 providers enrolled in the 340B Program, argued that the proposal would take away almost the entire 340B discount for many 340B drugs, especially brand name drugs (which they asserted were many of the drugs affected by the proposal). These commenters asserted that the Secretary does not have the authority to calculate and adjust 340B-acquired drug rates in this manner and noted that the standard 340B ceiling price for a brand name drug is AMP minus 23.1 percent, although the price can be lower if the drug's best price is lower or if the manufacturer increases the price of the drug more quickly than the rate of inflation. In addition, the commenters asserted that if a brand name drug's 340B ceiling price was based on the standard formula, the proposal would strip the hospital of nearly all its 340B savings because ''AMP has been found to be close to ASP.'' Thus, the commenters asserted, the proposed payment rate of ASP minus 22.5 percent is nearly identical to AMP minus 23.1 percent, leaving the hospital with ''virtually no 340B savings.''

Some commenters stated that the proposal mistakenly assumes that 340B hospitals purchase most 340B drugs at subceiling prices negotiated by the PVP. These commenters noted that some hospitals estimate that less than 10 percent of the drugs affected by the proposal are available at a subceiling price.

In addition, some commenters contended that subclause (I) of section 1833(t)(14)((A)(iii) establishes that the payment rate for subsequent years be set to the average acquisition cost of the drug taking into account hospital acquisition costs survey data collected through surveys meeting precise statutory requirements, and that such subclause does not provide adjustment authority for the agency. They stated that subclause (II) of section 1833(t)(14)((A)(iii) of the Act directs CMS, where acquisition cost data are not available, to set payment rates by reference to ASP provisions. Considered in context, the commenters stated that the statute reflects Congress's intent to limit CMS' authority to set payment rates and, consequently, is consistent with adjustment authority under subclause (II)—to convey only limited authority for any agency to adjust the payment rate. The commenters referred to *Roberts* v. *Sea-Land Servs., Inc.,* 566 U.S. 93, 101 (2012) (Statutory provisions ''. . . cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme'') to support their conclusions, although the commenters did not elaborate on the particular relevance of this case.

Finally, some commenters raised concern over the Secretary's use of the May 2015 MedPAC estimate as support for the 340B payment proposal. These commenters stated that the Secretary did not conduct his own independent analysis to support the payment proposal nor did he provide justification for use of MedPAC's analysis. One commenter stated that the Secretary cannot implement a payment cut of the magnitude proposed without providing a sufficient and replicable methodology that supports the proposal and that relying on a MedPAC analysis does not suffice for this ''important fiduciary, and legal, requirement.''

Response: We believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount. We disagree that this Medicare payment policy would effectively eviscerate the 340B Program and note that this proposal solely applies to applicable drug payments under the Medicare program; it does not change a hospital's eligibility for the 340B program. Further, under our proposal, we anticipate that the Medicare payment rate would continue to exceed the discounted 340B price the hospital received under the 340B program.

As previously stated, MedPAC's estimate of ASP minus 22.5 percent represents a lower bound estimate of the average minimum discount and the actual discount is likely much higher—up to 50 percent higher, according to some estimates, for certain drugs. In

some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). We did not receive public comments suggesting an alternative minimum discount off the ASP that would better reflect the hospital acquisition costs for 340B-acquired drugs. We believe this is notable because hospitals have their own data regarding their own acquisition costs, as well as data regarding OPPS payment rates for drugs. The fact that hospitals did not submit comments suggesting an alternative minimum discount that would be a better, more accurate reflection of the discount at issue is instructive for two reasons. One, it gives us confidence that our suggested payment of ASP minus 22.5 percent is, in fact, the low bound of the estimate and keeps Medicare payment within the range where hospitals will not be underpaid for their acquisition costs of such drugs. Two, it gives us confidence that the affected hospital community does not believe there is some other number, such as ASP minus 24 percent or ASP minus 17 percent, that would be a better, more accurate measure of what Medicare Part B should pay for drugs acquired at a discount through the 340B Program. Given the limitations in calculating a precise discount for each OPPS separately payable drug, we did not attempt to do so for the proposed rule. Instead, we stated that we believed that using the analysis from the MedPAC report is appropriate because MedPAC's estimate is based on all drugs separately paid under the OPPS except for vaccines, which are not eligible for 340B prices. Furthermore, the analysis is publicly available and can be replicated by interested parties.

With respect to the comments about the PVP, as previously stated, by the end of FY 2015, the PVP had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price. Participation in the PVP is voluntary and free, and we are aware of no reason that an eligible entity would not participate.

Furthermore, we disagree that the Secretary's authority under section 1834(t)(14)(A)(iii)(II) of the Act to calculate and adjust drugs rates as necessary is limited to what some might consider minor changes and find no evidence in the statute to support that position. As previously stated, we believe that ASP minus 22.5 percent represents the average minimum discount that hospitals paid under the OPPS received for drugs acquired under the 340B Program and reiterate that, in many instances, the discount is much higher. Thus, we are using this authority to apply a downward adjustment that is necessary to better reflect acquisition costs of those drugs.

• *Authority To Vary Payment by Hospital Group*

Comment: Some commenters asserted that only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment ''by hospital group.'' These commenters suggested that, by including ''by hospital group'' in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II). They further commented that the subparagraph (II) methodology must apply to ''the drug,'' and CMS may not vary payment for the same drug based upon the type of hospital.

Response: We disagree with the commenters who argue that the proposed policy would exceed the Secretary's authority under the statute by inappropriately varying payments for drugs by ''hospital group'' because we rely on section 1833(t)(14)(A)(iii)(II) of the Act, even though the explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II). As noted above, we believe our authority under section 1833(t)(14)(A)(iii)(II) of the Act to ''calculate and adjust'' drug payments ''as necessary for purposes of this paragraph'' gives the Secretary broad discretion to adjust payments for drugs, which we believe includes an ability to adjust payment rates according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Although we acknowledge that hospitals are eligible to receive drugs at discounted rates under the 340B Program if they qualify as a ''covered entity'' for purposes of the 340B Program, not all drugs for which a covered entity submits a claim for payment under the OPPS are necessarily acquired under the 340B Program. The OPPS payment for those drugs not acquired under the 340B Program would continue to be paid at ASP+6 percent.

We also note generally that the OPPS statute authorized the Secretary to establish appropriate Medicare OPPS payment rates for covered outpatient drugs. After specifically setting forth the payment methodology for 2004 and 2005, Congress provided that the Secretary could set OPPS drug prices in one of two ways: Using the average acquisition cost for the drug for that year, or using the average price for that drug in the year. However, in either case, prices set using either benchmark may be adjusted by the Secretary. Such adjustments may occur under section 1833(t)(14)(A)(iii)(II) of the Act if the Secretary determines they are ''necessary for purposes of'' section 1833(t)(14) of the Act, and this paragraph of the Medicare OPPS statute repeatedly discusses terms like ''hospital acquisition cost'' and ''variation in hospital acquisition costs'', and specifically notes in one section that it is within the Secretary's authority to determine that the payment rate for one drug ''may vary by hospital group.'' It would be odd for Congress to have a significant delegation of authority to the Secretary, use these specific terms and considerations throughout section 1833(t)(14) of the Act, and then assume the Secretary is foreclosed from taking into account those considerations in adjusting ASP ''as necessary for purposes'' of section 1833(t)(14) of the Act. The Secretary is generally empowered to adjust drug prices ''as necessary'' for the overall purposes of section 1833(t)(14) of the Act, and there is nothing in section 1833(t)(14) of the Act to indicate the Secretary is foreclosed from varying Medicare OPPS payment for a drug, depending on whether a 340B hospital acquired that drug at such a substantially lower acquisition cost.

• *Authority To Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority To Base Payment on an Average Discount*

Comment: Some commenters, including a commenter representing teaching hospitals, stated that the Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs. In addition, the commenters stated that section 1833(t)(14) of the Act requires the Secretary to rely on an average of acquisition cost data and sales prices for a given drug, not an average discount that is applied to all drugs acquired under the 340B Program.

One commenter stated that the Secretary impermissibly conflates the two alternative methods for setting payment rates, ''essentially discarding Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys.'' This commenter asserted that the Secretary is using MedPAC's estimate of average discounts as a proxy

or replacement for the surveys required under subsection (iii)(I).

Response: We disagree that section 1833(t)(14)(A)(iii)(II) of the Act requires use of survey data and note that, unlike subclause (I) of this section, subclause (II) does not require taking survey data into account for determining average price for the drug in the year. We continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Moreover, under section 1833(t)(14)(A) of the Act, there still will be one starting, baseline price for an applicable drug, that is, the rate that applies under 1842(o), 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary. For drugs not acquired under the 340B Program, we will continue to utilize that price (ASP+6 percent), which as we have explained ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' However, for drugs acquired through the 340B Program, we are adjusting that price downward (ASP minus 22.5 percent) to more closely align with the hospital acquisition cost for a drug when purchased at a discounted price under the 340B Program. In the absence of acquisition costs from hospitals that purchase drugs through the 340B Program, we believe it is appropriate to exercise our authority to adjust the average price for 340B-acquired drugs, which are estimated to be acquired at an average minimum discount of ASP minus 22.5 percent. Importantly, because we are not using authority under section 1833(t)(14)(A)(iii)(I) of the Act (as the commenter suggested), we disagree with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

• *Current Agency View Contrasts With Longstanding Practice*

Comment: Some commenters contended that the proposal contrasts sharply with the agency's previous view and longstanding practice of applying the statutory scheme of section 1833(t)(14) of the Act. These commenters noted that since CMS began relying on subclause (II) in 2012 to set the payment rate, the agency has never invoked the discretionary authority. The commenters stated that, instead, CMS stated that the statutory default of ASP+6 percent ''requires no further adjustment'' because it ''represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.'' Moreover, the commenters added, CMS has applied the statutory default rate without further adjustment in each subsequent year. They asserted that the CY 2018 proposal, in contrast, departs dramatically from longstanding prior practice and adopts a substantially reduced payment rate of ASP minus 22.5 percent for drugs acquired under a 340B Program.

Response: As discussed in the earlier background section, section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary authority to adjust, as necessary for purposes of paragraph (14) of section 1833(t) of the Act, the applicable payment rate for separately payable covered outpatient drugs under the OPPS. Specifically, we believe that the proposed reduced payment for 340B-acquired drugs would meet the requirements under section 1833(t)(14)(A)(iii)(II) of the Act, which states that if hospital acquisition cost data are not available, the payment for an applicable drug shall be the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph* (paragraph (14) of section 1833(t) of the Act) (emphasis added). We do not have hospital acquisition cost data for 340B drugs and, therefore, we proposed to continue to pay for these drugs under the methodology in our authority at section 1833(t)(14)(A)(iii)(II) of the Act which we determined to be ASP, and then to adjust that amount by applying a reduction of 22.5 percent to that payment methodology, which, as explained throughout this section, is the adjustment we believe is necessary to more closely align with the acquisition costs for drugs acquired under the 340B Program.

As previously stated, we believe that using an average discount to set payment rates for separately payable 340B-acquired drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs and (2) protecting the confidential nature of discounts applied to a specific drug. Furthermore, our proposed and finalized policy will lower OPPS payment rates for Medicare beneficiaries who receive drugs at hospitals subject to the 340B payment reduction.

In addition, we do not believe that the fact that we have not historically utilized our adjustment authority under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs means we are permanently barred from adjusting these payments where, as here, we have provided a reasoned explanation for doing so. We continue to believe, as the commenter noted, that ASP+6 percent requires no further adjustment for drugs that are not acquired under the 340B Program because, at this time, we have not found similar evidence of the difference between the statutory benchmark (ASP+6 percent) and average hospital acquisition costs for such drugs. However, that is not the case for 340B-acquired drugs. As explained in detail throughout this section, we believe that a payment amount of ASP minus 22.5 percent for drugs acquired under the 340B Program is better aligned to hospitals' acquisition costs and thus this adjustment, for drugs acquired under the 340B Program, is necessary for Medicare OPPS payment policy.

• *Violation of Section 340B of the Public Health Service Act*

Comment: Some commenters stated that the proposed payment reduction would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts. One commenter asserted that the payment proposal would ''hijack Congress' carefully crafted statutory scheme by seizing 340B discounts from hospitals and transferring the funds to providers that Congress excluded from the 340B Program,'' thereby violating section 340B of the Public Health Service Act. The commenter further noted that discounts under the 340B Program are only available to ''covered entities'' that are defined by law and that Congress thus intended the benefits of the program to accrue to these providers only. The commenter contended that Congress' reference to Medicare definitions when describing covered entities demonstrates that it considered the Medicare program when it adopted the 340B Program and decided not to grant discounts to all Medicare hospitals. Rather, the commenter believed that Congress made a deliberate decision to limit the benefits of the 340B Program only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients. In addition, the commenter stated that when Congress has intended Federal health care programs to intrude upon the 340B Program, it has been crystal clear.

In contrast, commenters asserted that Congress has been wholly silent on the relationship between 340B and Medicare Part B, which indicates Congress's intent that Medicare should not ''encroach'' upon the 340B Program

by ''redistributing [340B] discounts to non-340B providers.'' The commenters noted that the 340B statute and Medicare have coexisted for several years and that Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. As an example, the commenters cited legislation enacted in 2010, in which Congress amended both the 340B and the Medicare statutes, but did not authorize CMS to redistribute 340B savings to non-340B hospitals or to Part B generally.

Commenters further asserted that the proposed cut to 340B hospitals is also contrary to Congress's intent for the 340B Program to enable safety-net providers to reach more patients and furnish more comprehensive services and would undermine this purpose by preventing the operation of the 340B statute. These commenters suggested that, although manufacturers would still have to give 340B discounts, 340B participating hospitals would receive no benefit from those discounts; thus, the statutory purpose of 340B would be fatally undermined.

Response: We do not believe that this proposal under section 1833(t) of the Act is in conflict with section 340B of the Public Health Service Act. Section 1833(t) of the Act governs Medicare payment policies for covered hospital outpatient department services paid under the OPPS, while section 340B of the Public Health Service Act governs eligibility and program rules for participation in the 340B Program. There are no references in either section of law to each other. In fact, the failure of either statute to reference the other proves the opposite—that each statute stands on its own and neither is hindered or rendered null and void by the other. There is no requirement in the Public Health Service Act that the 340B Program ''guarantee'' or provide a certain profit from the Medicare program. Likewise, there is no requirement in section 1833(t) of the Act to pay a particular rate for a hospital enrolled in the 340B Program. We agree with the commenters that Congress was aware of both the 340B Program and the OPPS and of the programs' relationships to one another. However, we believe that the silence of each statute with respect to the other should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPS.

Furthermore, we are unaware of legislative history or other evidence to corroborate the commenters' belief that Congress' silence on the relationship between 340B and Medicare Part B OPPS payments should be viewed as constraining the Secretary's ability under section 1833(t)(14) of the Act as to how to calculate payment rates for drugs acquired under the 340B Program under the OPPS. While legislative silence can be difficult to interpret, we note that Congress' silence regarding the 340B Program in enacting Medicare OPPS payment for certain drugs would create the opposite inference. The 340B Program existed well before Congress enacted the Medicare OPPS and payment for certain drugs. If Congress wanted to exempt 340B drugs or entities with a 340B agreement from Medicare OPPS payment for drugs generally, it easily could have done so. Instead, Congress provided for Medicare OPPS drug payments ''as calculated and adjusted by the Secretary as necessary,'' without any mention of, or restriction regarding, the already existent 340B Program.

We also disagree with commenters who believe that implementing the OPPS payment methodology for 340B-acquired drugs as proposed will ''eviscerate'' or ''gut'' the 340B Program. As discussed earlier in the background section, the findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. As stated in the proposed rule, we believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program.

With respect to the comment that the proposal would frustrate the intent of the 340B Program and redirect Medicare payments to other hospitals that do not participate in the 340B Program, we reiterate that we proposed to redistribute the savings in an equal and offsetting manner to all hospitals paid under the OPPS, including those in the 340B Program, in accordance with the budget neutrality requirements under section 1833(t)(9)(B) of the Act. However, we remain interested in exploring ways to better target the offsetting amount to those hospitals that serve low-income and uninsured patients, as measured by uncompensated care. Details on the redistribution of funds are included in section XVIII. of this final rule with comment period.

• Proposal Is Procedurally Defective and Inconsistent With Advisory Panel Recommendations

Comment: Some commenters contended that the proposal is procedurally defective under the OPPS statute. The commenters asserted that the Secretary's justification for the proposed reduced rate rests, in part, on intertwined issues related to clinical use and hospital cost of drugs. The commenters objected to CMS' reference to studies suggesting that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals as support for proposing a payment rate that eliminates the differential between acquisition cost and Medicare payment. These commenters cited other studies in an effort to refute the evidence presented in the proposed rule.[29] [30] The commenters believed that CMS should have asked the HOP Panel to consider the intertwined issues of drug cost and clinical use prior to making a proposal to reduce payment for 340B-acquired drugs, and the Secretary should have consulted with the HOP Panel in accordance with section 1833(t)(9)(A) of the Act, as part of the process of review and revision of the payment groups for covered outpatient department services and the relative payment weights for the groups. The commenters argued that, because the Secretary did not consult with the HOP Panel before publishing its 340B payment proposal, the Secretary acted contrary to the statute. The commenters noted that at the August 21, 2017 meeting of the HOP Panel that occurred after publication of the proposed rule, the Panel urged that CMS not finalize the proposed payment reduction.

At the August 21, 2017 meeting of the HOP Panel, the Panel made the following recommendations with respect to the proposed policy for OPPS payment for drugs acquired under the 340B Program:

The Panel recommended that CMS:

• Not finalize its proposal to revise the payment rate for drugs purchased under the 340B Program;

• Collect data from public comments and other sources, such as State

[29] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: *http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf*.

[30] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: *http://www.340bhealth.org/files/LowIncomeOncology.pdf*;

Medicaid programs in Texas and New York, on the potential impact of revising the payment rate, implementing a modifier code, and the effects of possible mechanisms for redistributing the savings that result from changing the payment rate; and

• Assess the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved.

In addition, one commenter suggested that the proposal was ''procedurally defective'' because the proposal was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR). The commenter asserted that the proposal cannot be implemented without a change to the Medicare regulations and stated that the Medicare statute requires CMS to issue regulations when altering the substantive standards for payment.[31] The commenter stated that the proposal falls squarely within this requirement because it would change the substantive legal standard governing payments to 340B hospitals for separately payable drugs.

Another commenter stated that CMS' proposal also violates section 1833(t)(2)(E) of the Act because the agency is not authorized and did not offer a reasoned basis for applying savings achieved as a result of its proposal to reduce significantly payments to 340B hospitals to Part B services generally. Likewise, a few commenters stated that the Administrative Procedure Act (APA) requires the Secretary to offer a ''reasoned basis'' for proposing to take an unprecedented action. The commenters suggested that, as a matter of longstanding policy and practice, the Secretary has never applied such a sweeping change to drug rates nor has it ever applied savings from OPPS outside of the OPPS.

Response: We remind the commenters that our proposal was based on findings that ASP minus 22.5 percent reflects the minimum average discount that hospitals in the 340B Program receive. We are familiar with the reports the commenters referenced in their comments. However, we continue to believe, based on numerous studies and reports, that 340B participation is not well correlated to the provision of uncompensated care and is associated with differences in prescribing patterns and drug costs. For example, as noted earlier in this section, GAO found that ''in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals,'' thus indicating that, on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis.

With respect to the HOP Panel, we believe that this comment reflects a misunderstanding of the Panel's role in advising the Secretary. Section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

The provisions described under section 1833(t)(9)(A) of the Act do not impose an obligation on the Secretary to consult with the HOP Panel *prior* to issuing a notice of proposed rulemaking nor do they require the Secretary to adopt the Panel's recommendation(s). Rather, the statute provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Secretary met the requirement of section 1833(t)(9)(A) of the Act at the HOP Panel August 21, 2017 meeting in which the Panel made recommendations on this very proposed policy. The HOP Panel's recommendations, along with public comments to the proposed rule, have all been taken into consideration in the development of this final rule with comment period.

While we are not accepting the HOP Panel's recommendation not to finalize the payment reduction for drugs purchased under the 340B Program, as discussed later in this section, we are modifying our position on the modifier in an effort to ease administrative burden on providers, taking into account the way in which the modifier is used in several State Medicaid programs, as the Panel recommended. In addition, we have collected data from public comments on the potential impact of revising the payment rate, implementing a modifier, and the effects of possible mechanisms for redistributing the ''savings'' (or the dollars that result) from changing the payment rate and have assessed the regulatory burden of changing the payment rate and the potential impact on 340B hospitals of redistributing dollars saved, all of which were steps the HOP Panel recommended we take.

Regarding the comments asserting that the Secretary is out of compliance with procedures used to promulgate regulations as described under section 1871 of the Act (42 U.S.C. 1395hh), we note that we have received public comments on our interpretation of the Medicare statute, and we respond to those comments above. We further note that we did not establish in the Code of Federal Regulations the rates for separately payable, nonpass-through drugs and biologicals in past rulemakings. Because we have not adopted regulation text that prescribes the specific payment amounts for separately payable, nonpass-through drugs and biologicals, there was no regulation text to amend to include our proposed payment methodology for drugs acquired under the 340B Program. However, this does not mean that payment rates for separately payable drugs were not available to the public. That information is available in Addendum B to this final rule with comment period, which lists the national payment rates for services paid under the OPPS, including the payment rates for separately payable drugs and biologicals based on ASP+6 percent. We note that we have not provided the reduced payment rates for separately payable drugs and biologicals acquired under the 340B Program in Addendum B, but hospitals can arrive at those rates using the ASP+6 percent rate that is included in Addendum B. Finally, with respect to comments on redistribution of the dollars that result from the 340B payment policy, we are finalizing our proposal to achieve budget neutrality for the payment reduction for 340B-acquired drugs through an increase in the conversion factor. We disagree that our proposal to apply budget neutrality in accordance with section 1833(t)(9)(B) of the Act violates the APA or statutory authority. Further, we note that if we decide to take a different approach with respect to the redistribution of funds for budget neutrality in the future, we will consider such approach in future rulemaking.

• Impact on Medicare Beneficiary Cost-Sharing

Comment: Some commenters noted that Medicare beneficiaries, including dual-eligible Medicare beneficiaries,

[31] ''No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation. . . .'' Section 1871 of the Social Security Act (42 U.S.C. 1395hh).

would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part. These commenters asserted that the proposal would actually increase their out-of-pocket costs for other Part B benefits.

Response: The cost-sharing obligation for Medicare beneficiaries is generally 20 percent of the Medicare payment rate. While many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on behalf of the beneficiary. While we are implementing this policy in a budget neutral manner equally across the OPPS for CY 2018 for non-drug items and services, we may revisit how any savings from the lowered drug payment rate for 340B drugs may be allocated in the future and continue to be interested in ways to better target the savings to hospitals that serve the uninsured and low-income populations or that provide a disproportionate share of uncompensated care.

In addition, as noted earlier in this section, in the hospital setting, not only are beneficiaries liable for cost-sharing for drugs they receive, but they also incur a ''facility fee'' solely because the drug was furnished in the hospital setting. As described in section II.A.3.b. of this final rule with comment period, for CY 2018, we are adopting a policy to conditionally package Level 1 and Level 2 drug administration services and believe that these steps taken together may help encourage site-neutral care in that beneficiaries may receive the same drugs and drug administration services at the physician office setting without a significant difference in their financial liability between settings.

• *Calculation of Savings*

Comment: Commenters disagreed with CMS' impact estimate and a few commenters provided their own analysis of the 340B drug payment proposal. One commenter believed that even if CMS implements the policy as proposed, in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, payments for non-drug APCs would increase across hospitals by approximately 3.7 percent (in contrast to CMS' estimate of 1.4 percent). According to the commenter, this redistribution would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million. The commenter asserted that CMS' proposal would remove $800 million intended to support what it referred to as the congressionally mandated mission of 340B hospitals from these already vulnerable facilities and redistribute these dollars to other hospitals that do not participate in the 340B Program. Likewise, the commenter challenged CMS' suggested alternative approaches to achieving budget neutrality, such as applying offsetting savings to specific services within the OPPS or outside of the OPPS to Part B generally (such as to physician services under the Medicare Physician Fee Schedule), which the commenter believed would similarly penalize these most vulnerable hospitals and inhibit their efforts to carry out the purpose of the 340B Program. Finally, other commenters noted that implementing the proposed policy in a non-budget neutral manner would effectively ''gut'' the 340B Program.

Response: With respect to comments on the proposed distribution of savings, we refer readers to section XVIII. of this 2018 OPPS/ASC final rule with comment for discussion on the redistribution of savings that result from the estimated impact of the 340B policy as well as calculation of budget neutrality. Briefly, for CY 2018, we are implementing the alternative payment methodology for drugs purchased under the 340B Program in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor for nondrug services. Therefore, the resulting savings from the 340B payment policy will be redistributed pro rata through an increase in rates for non-drug items and services under the OPPS. We have already addressed comments relating to the assertion that our proposal would ''gut'' or ''eviscerate'' the 340B Program. Likewise, we have addressed the interaction between our authority under section 1833(t)(14)(A) of the Act relative to section 340B of the Public Health Service Act in our responses above.

(3) Other Areas

Comment: MedPAC commented reiterating its recommendations to Congress in its March 2016 Report to the Congress. Specifically, MedPAC commented that it recommended that payment rates for all separately payable drugs provided in a 340B hospital should be reduced to 10 percent of the ASP rate (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to the Congress that savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured, and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status.

Response: We thank MedPAC for its comments and for its clarification that its recommendation that ''[t]he Congress should direct the Secretary of the Department of Health and Human Services to reduce Medicare payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the average sales price (ASP)'' was intended to be 10 percent lower than the current Medicare rate of ASP+6 percent and would result in a final OPPS payment of ASP minus 5.3 percent when taking the sequester into account. However, we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B participating hospitals. In its May 2015 Report to the Congress, MedPAC estimated that the average minimum discount for a 340B hospital paid under the OPPS was ASP minus 22.5 percent, which it noted was a conservative, ''lower bound'' estimate. Further, in its March 2016 Report to the Congress, MedPAC stated that, ''[i]n aggregate, the Office of Inspector General (OIG) estimates that discounts across all 340B providers (hospitals and certain clinics) average 34 percent of ASP, allowing these providers to generate significant profits when they administer Part B drugs (MedPAC March 2016 Report to Congress, page 76). MedPAC further noted the estimate of the aggregate discount was based on all covered entities (hospitals and certain clinics).

Because 340B hospitals accounted for 91 percent of Part B drug spending for all covered entities in 2013, it is reasonable to assume that 340B hospitals received a discount similar to 33.6 percent of ASP (MedPAC March 2016 Report to Congress, page 79).

Further, as we stated in the proposed rule, the GAO reported that the amount of the 340B discount ranges from an estimated 20 to 50 percent discount, compared to what the entity would have otherwise paid to purchase the drug. In addition, voluntary participation in the PVP results in a covered entity paying a subceiling price on certain covered outpatient drugs (estimated to be approximately 10 percent below the ceiling price). (U.S. Department of Health and Human Services, HRSA FY 2018 Budget Justification)

Accordingly, we continue to believe that ASP minus 22.5 percent represents a conservative estimate of the average minimum discount that 340B-enrolled hospitals paid under the OPPS receive for drugs purchased with a 340B Program discount and that hospitals likely receive an even steeper discount on many drugs, especially brand name drugs. We also continue to believe that section 1833(t)(14)(A)(iii)(II) of the Act allows the Secretary to make adjustments, if hospital acquisition cost data is not available, as necessary, so that the Medicare payment rate better represents the acquisition cost for drugs and biologicals that have been acquired with a 340B discount.

With respect to MedPAC's comment regarding targeting the savings to uncompensated care, we refer readers to section XVIII.A.5. of this final rule with comment period.

• Comments Regarding Rural Hospitals

Comment: Commenters representing rural hospitals, particularly RRCs and SCHs, expressed opposition to the proposal, noting that it could be especially harmful to rural hospitals in light of the ''hospital closure crisis.'' One commenter cited a report from a health analytics company and noted that since 2010, 80 rural hospitals have closed and that one-third of remaining rural hospitals are vulnerable to closure, with 41 percent of rural hospitals operating at a financial loss.

Commenters noted that rural hospitals enrolled in the 340B Program depend on the drug discounts to provide access to expensive, necessary care such as labor and delivery and oncology infusions. The commenters stated that rural Americans are more likely to be older, sicker, and poorer than their urban counterparts. The commenter gave examples of rural hospitals that have used profit margins on 340B-acquired drugs to offset uncompensated care and staff emergency departments. In addition, the commenters stated that a portion of rural hospitals are excluded from purchasing orphan drugs through the 340B Program. Therefore, the commenters stated, these hospitals often use their 340B savings to offset the expense of purchasing orphan drugs, which they note comprise a growing number of new drug approvals.

In addition, a commenter representing several 340B-enrolled hospitals stated that multiple hospitals report that the 340B Program is the reason the hospital can provide oncology infusions in their local community and that the chemotherapy infusion centers tend to be small with variation in patients served based on the needs of the community. The commenter stated that, without the 340B Program, many rural hospitals would likely need to stop providing many of the outpatient infusions, thereby forcing patients to either travel 35 miles (in the case of SCHs which must generally be located at least 35 miles from the nearest like hospital) to another facility or receive care in a hospital inpatient setting, which is a more costly care setting. Another commenter, a member of Congress representing a district in the State of Ohio, commented that while the 340B Program is in need of reform, the program remains an important safety net for rural hospitals in Ohio and around the country. The commenter stated that 340B hospitals offer safety-net programs to their communities, including opioid treatment programs, behavioral health science programs, and others. The commenter further stated that the 340B drug payment proposal did not address broader structural issues with the 340B Program itself, including lack of oversight and clear guidance and definitions, and that the proposal could harm the hospitals that the 340B Program was intended to help. In addition, the commenter noted that ''arbitrary cuts'' to the 340B Program for safety-net hospitals could have detrimental impacts on the economic growth and opportunities in the communities those hospitals serve and that the proposal does not advance the larger goals of 340B Program reform.

One commenter noted that SCHs face 47.5 percent higher levels of bad debt and 55 percent lower profit margins. Thus, even with 340B discounts, the commenter argued that rural hospitals like rural SCHs are financially threatened. Commenters also noted that rural hospitals are typically located in lower income economic areas and are not able to absorb the proposed reduction in drug payment for 340B purchased drugs. Moreover, commenters suggested that the proposal disproportionately impacts rural hospitals compared to its effect on urban hospitals.

Finally, commenters requested that, if CMS finalizes the policy as proposed, CMS exempt hospitals with a RRC or SCH designation from the alternative 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as ''economic engines'' for many rural communities.

Response: We share commenters' concerns about access to care, especially in rural areas where access issues may be even more pronounced than in other areas of the country. We note our proposal would not alter covered entities' access to the 340B Program. The alternative 340B drug payment methodology solely changes Medicare payment for 340B-acquired drugs.

Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

In the CY 2018 OPPS/ASC proposed rule, we sought public comment for future policy refinements on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments for drugs acquired under the 340B program. Taking into consideration the comments

regarding rural hospitals, we believe further study on the effect of the 340B drug payment policy is warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. In particular, given challenges such as low patient volume, it is important that we take a closer look at the effect of an ASP minus 22.5 percent payment on rural SCHs.

With respect to RRCs, we note that there is no special payment designation for RRCs under the OPPS. By definition, RRCs must have at least 275 beds and therefore are larger relative to rural SCHs. In addition, RRCs are not subject to a distance requirement from other hospitals. Accordingly, at this time, we are not exempting RRCs from the 340B payment adjustment.

For CY 2018, we are excluding rural SCHs (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in the CY 2019 OPPS rulemaking.

• Children's and PPS-Exempt Cancer Hospitals

Comment: Commenters representing children's hospitals (''children's'') raised objections to the proposal because of the potential impact on the approximate 8,000 children with end-stage renal disease (ESRD) who are eligible for Medicare. One commenter cited that currently 48 children's hospitals participate in the 340B Program and rely on the savings the program provides to enhance care for vulnerable children. According to the commenter, pediatric ESRD patients require high levels of care and rely on life-saving pharmaceuticals that often come at a high cost. Therefore, the commenters posited that it is because children's patients are more expensive to treat and not because of inappropriate drug use that 340B hospitals incur higher drug expenditures. In addition, the commenters expressed concern with the effect the 340B drug payment policy may have on State Medicaid programs, considering Medicaid is the predominant payer type for children's hospitals. The commenters requested that, unless CMS is able to examine the impact on pediatric Medicare beneficiaries, CMS should exempt children's hospitals from the alternative 340B drug payment methodology.

An organization representing PPS-exempt cancer hospitals commented that CMS' proposal would severely harm the hospitals that treat the most vulnerable and underserved patients and communities, undermining these hospitals' ability to continue providing programs designed to improve access to services. The commenter believed that assumptions alluded to in the CY 2018 OPPS/ASC proposed rule, which suggested that providers are abusing the savings generated from the 340B Program or potentially creating incentives to over utilize drugs, are inaccurate and that clinicians provide the care that is necessary to treat a patient's disease. The commenter suggested that CMS work with, or defer to, HRSA to first conduct a complete analysis of how the 340B Program is utilized for the benefit of patients prior to proposing any changes to Medicare payment for drugs purchased through the program.

Response: We share the commenters' views on protecting access to high quality care for all Medicare beneficiaries, including those treated in children's or PPS-exempt cancer hospitals. Further, because of how these classes of hospitals are paid under the OPPS, we recognize that the 340B drug payment proposal may not result in reduced payments for these hospitals in the aggregate.

Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. That is, these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure.

Accordingly, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology for CY 2018. Therefore, for CY 2018, we are excluding children's and PPS-exempt cancer hospitals from the alternative 340B drug payment policy. As discussed in a later section in this final rule with comment period, because we are redistributing the dollars in a budget neutral manner within the OPPS through an offsetting increase to the conversion factor, children's hospitals and PPS-exempt cancer hospitals will receive a higher payment when providing a non-drug service.

In summary, we are adopting for CY 2018 an exemption for rural SCHs, children's hospitals, and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology. These three types of hospitals will not be subject to a reduced drug payment for drugs that are purchased under the 340B Program in CY 2018. We may revisit the specific types of hospitals excluded, if any, from the 340B payment policy in CY 2019 rulemaking. However, as discussed in more detail below, it remains important to collect information on which drugs being billed to Medicare were acquired under the 340B Program. Accordingly, these three types of hospitals will still be required to report an informational modifier ''TB'' for tracking and monitoring purposes. We may revisit this 340B drug payment policy, including whether these types of hospitals should continue to be excepted from the reduced Medicare payment rate, in future rulemaking.

• Biosimilar Biological Products

Comment: Some commenters expressed opposing views about applying the proposed 340B payment methodology to biosimilar biological products. One pharmaceutical manufacturer recommended that the Secretary use his equitable adjustment authority at section 1833(t)(2)(E) of the Act to apply a narrow equitable adjustment to biosimilar biological products with pass-through payment status to pay for these drugs at ASP minus 22.5 percent of the reference product rather than ASP+6 percent of the reference product. The commenter asserted that excluding biosimilar biological products from the alternative 340B payment methodology would result in a significant payment differential between biosimilar biological products and reference products which may cause providers to switch patients to different products for financial reasons, rather than clinical factors. The commenter stated that, if the policy is implemented as proposed, the competitive biosimilar marketplace would significantly change because Medicare would pay more for the biosimilar biological product with pass-through payment status and weaken market forces. The commenter estimated that if the 340B drug policy is implemented as proposed, up to $50 million of any savings could be lost due to hospitals switching to the biosimilar biological product on pass-through payment status (that will be paid at ASP+6 percent of the reference product). Moreover, the commenter pointed out that CMS' policy to only provide pass-through payments for the

first eligible biosimilar biological product of any reference biological would also create a similar payment disadvantage for any subsequent biosimilar biological product, which would be ineligible for pass-through payment under CMS' policy.

Another commenter, a different pharmaceutical manufacturer, requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established. The commenter indicated that while a biosimilar biological product is less expensive to the Medicare program, hospitals are incented by the 340B Program to purchase the originator product because of ''the spread'' or payment differential with respect to the originator product. Moreover, the commenter stated that applying the proposed adjustment to payment for biosimilar biological products in certain hospitals will retain market share for the more expensive reference product that is further compounded by market practices of volume-based rebates and exclusionary contracts for the reference product.

Response: We understand the commenters' concerns. As discussed in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period, we are adopting the biosimilar biological products HCPCS coding established under the CY 2018 MPFS final rule. Briefly, we adopted a final policy to establish separate HCPCS codes for each biosimilar biological product for a particular reference product beginning January 1, 2018. In addition, we also stated in section V.B.2. of this CY 2018 OPPS/ASC final rule with comment period that we are making a conforming amendment to our pass-through payment policy for biosimilar biological products such that each FDA-approved biosimilar biological product will be eligible for transitional pass-through payment instead of only the first biosimilar for a particular reference product.

Therefore, given the policy changes affecting coding and payment for biosimilar biological products that we are adopting in the CY 2018 MPFS final rule and this CY 2018 OPPS/ASC final rule with comment period, we disagree with the commenters that we should exclude biosimilar biological products from the 340B payment policy or use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to adjust payment to ASP minus 22.5 percent of the reference product for biosimilar biological products with pass-through payment status. We believe the statutory provision on transitional drug pass-through payment under section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs eligible for pass-through payment. Therefore, we are unable to accept the commenter's request to pay a biosimilar biological product on pass-through payment status the reduced 340B payment rate. We are adopting a policy that any biosimilar biological product with pass-through payment status will be exempt from the alternative payment methodology for 340B drugs and will continue to be paid at ASP+6 percent of the reference product. Biosimilar biological products that are not on pass-through payment status will be paid ASP minus 22.5 percent of the reference product. We believe it is appropriate to pay this amount for biosimilar biological products as it is consistent with the amount paid for non-340B-acquired biosimilar biological products, which is ASP+6 percent of the reference product. Currently, there are two biosimilar biological products available on the market and both are on pass-through payment status for the entirety of CY 2018. Therefore, no biosimilar biological products currently available will be affected by the alternative payment methodology for 340B-acquired drugs for CY 2018. We recognize the concerns about paying different rates for similar drugs and biologicals and continue to assess the feasibility and practicality of an alternative 340B payment adjustment for biosimilar biological products in the future.

- Nonexcepted Off-Campus Hospital Outpatient Departments

Comment: A few commenters noted that CMS' proposed alternative payment methodology for 340B purchased drugs would not apply to nonexcepted off-campus provider-based departments (PBDs) of a hospital and could result in behavioral changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of the Bipartisan Budget Act of 2015. Commenters recommended that, if CMS adopts a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs are acquired under the 340B Program. In addition, the commenters believed that because CMS did not propose to limit the expansion of services or volume increases at excepted off-campus PBDs, CMS will create financial incentives for hospitals to shift or reallocate services to the site of care that pays the highest rate for an item or service.

Response: We appreciate the commenter's concerns about potential unintended consequences of our proposal. We will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs as we continue to explore whether to pursue future rulemaking on the issues of clinical service line expansion or volume increases, and other related section 603 implementation policies.

In the CY 2017 OPPS/ASC final rule with comment period, we discussed the provision of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 144–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered outpatient department services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met (81 FR 79699). We issued an interim final rule with comment period along with the CY 2017 OPPS/ASC final rule with comment period to establish the MPFS as the ''applicable payment system,'' which will apply in most cases, and payment rates under the MPFS for non-excepted items and services furnished by nonexcepted off-campus outpatient provider based departments (PBDs) (81 FR 79720). (Other payment systems, such as the Clinical Laboratory Fee Schedule, continue to apply in appropriate cases.) That is, items and services furnished by nonexcepted off-campus outpatient PBDs, are nonexcepted items and services that are not covered outpatient services, and thus, are not payable under the OPPS. Rather, these nonexcepted items and services are paid ''under the applicable payment system,'' which, in this case, is generally the MPFS.

As we discussed in the CY 2017 OPPS/ASC interim final with comment period (81 FR 79718) and reiterated in the CY 2018 MPFS final rule, payment for Part B drugs that would be separately payable under the OPPS (assigned status indicator ''K'') but are not payable under the OPPS because they are furnished by nonexcepted off-campus outpatient PBDs will be paid in accordance with section 1847A of the Act (generally, ASP+6 percent),

consistent with Part B drug payment policy in the physician office. We did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking.

• Data Collection and Modifier

Comment: The vast majority of commenters objected to CMS' intention to require hospitals that *do not* purchase a drug or biological through the 340B program to apply a modifier to avoid a reduced drug payment. A few commenters supported the modifier proposal. The commenters who disagreed with proposal stated that it would place an unnecessary administrative and financial burden on hospitals that do not participate or are not eligible to participate in the 340B Program. Similarly, the commenters stated that the modifier requirement as described in the proposed rule would put a financial and administrative strain on hospitals with fewer resources. In addition, the commenters contended that a requirement for hospitals to report a modifier for drugs that were not acquired under the 340B Program would place hospitals at significant risk for noncompliance if not implemented correctly, which many commenters believe is nearly impossible to do. As an alternative approach, numerous commenters recommended that CMS require hospitals that *do* purchase a drug under the 340B Program to report the modifier, rather than those that do not.

Regarding a January 1, 2018, implementation date for the modifier, some commenters expressed concern and doubted their ability to implement the modifier as described in the proposed rule accurately. The commenters indicated that additional time would be needed to adapt billing systems, allow for testing of claims reported with the modifier, and educate staff. Based on discussion of how the modifier would work in the proposed rule, the commenters stated that hospitals would either have to append the modifier to the claim at the time the drug is furnished, or retroactively apply the modifier, thus delaying claims submission to Medicare.

The commenters provided detailed descriptions on hospital pharmacy set up, including information on software tools to support inventory management of drugs dispensed to 340B and non-340B patients (based on HRSA definition of an eligible patient). One commenter indicated that the drug supply system used for purchasing covered outpatient drugs is completely separate from—and does not necessarily communicate with—the hospital's pharmacy drug dispensing and patient billing systems. While these software tools enable split-billing to distinguish 340B and non-340B patients, the commenters noted that this patient determination is typically not done in real time when a drug is administered. Commenters noted that 340B hospitals that use split-billing software do not receive information on 340B patient status on a daily basis and the proposal could result in delayed billing. The commenters stated that hospitals typically make these determinations retrospectively and it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. The commenters noted that, under this ''replenishment model,'' hospitals track how many 340B-eligible drugs are used, and once enough drugs are dispensed to complete a package, they will replenish the drug at the 340B rate. As such, the commenters argued that hospitals do not know when the drug is dispensed whether it will cost them the 340B rate or the wholesale acquisition cost (WAC). Therefore, the commenters expressed concern that the modifier requirement as described in the proposed rule would result in billing delays and, for some hospitals, may cause a short-term interruption in cash flow.

In addition, the commenters requested that, while the payment reduction would apply to nonpass-through separately payable drugs purchased with a 340B discount, CMS accept the modifier when reported with drug HCPCS codes that are packaged (and for which no separate payment will be made) to reduce or prevent operational burden that may be caused if affected providers have to determine on a claim-by-claim basis whether a drug is eligible for separate payment.

With respect to State Medicaid programs that also require a modifier to identify 340B-purchased drugs on outpatient claims, the commenters noted that CMS' proposal would be counter to Medicaid requirements and would create confusion and add complexity for providers who treat Medicaid recipients in multiple states. The commenters reported that many State Medicaid programs require a modifier to identify drugs that were purchased under 340B to administer their Medicaid drug rebate programs to prevent duplicate discounts on 340B drugs. The commenters suggested that if CMS reversed its position on application of the modifier, it would ensure crossover claims (claims transferred from Medicare to Medicaid) are correctly interpreted by State Medicaid programs so that they can appropriately request manufacturer rebates on drugs not purchased under the 340B Program. Moreover, some commenters believed that if CMS required the modifier to be reported for 340B-purchased drugs, State Medicaid programs would also adopt the modifier, leading to national uniformity in reporting of 340B drugs.

Finally, in the event that CMS required the modifier on claims for 340B drugs, rather than non-340B drugs, commenters sought clarity on whether the modifier applies only to drugs purchased under the 340B Program which are subject to a ceiling price payment from the manufacturer or if the modifier would also apply to drugs purchased by a 340B-registered facility, but purchased under the Prime Vendor Program for which only 340B facilities are eligible. One commenter asked that CMS emphasize that 340B pricing is not available on drugs furnished to hospital inpatients.

Response: We appreciate the detailed comments that were submitted. As noted in the proposed rule, we did not propose to establish the modifier but rather noted our intent to establish the modifier, regardless of whether we adopted the alternative payment methodology for drugs acquired through the 340B Program. However, we are responding to some of the comments submitted in this final rule with comment period with information on this modifier that we believe is important to communicate as soon as possible. We will consider whether additional details will need to be communicated through a subregulatory process, such as information posted to the CMS Web site.

After considering the administrative and financial challenges associated with providers reporting the modifier as described in the CY 2018 OPPS/ASC proposed rule, and in order to reduce regulatory burden, we are reversing our position on how the modifier will be used by providers to effectuate the payment adjustment for 340B-purchased drugs.

Specifically, beginning January 1, 2018, providers who are not excepted from the 340B payment adjustment will report modifier ''JG'' (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug *was* acquired under the 340B Program. This requirement is aligned with the modifier requirement already mandated in several States under their Medicaid programs. Therefore, we believe that this option will pose less of an administrative burden. Further, having

consistent application of the modifier being required for a drug that was purchased under the 340B Program instead of a drug not purchased under the 340B Program will help improve program integrity by helping ensure that hospitals are not receiving ''duplicate discounts'' through both the Medicaid rebate program and the 340B Program. The phrase ''acquired under the 340B Program'' is inclusive of all drugs acquired under the 340B Program or PVP, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program should not be reported with the modifier ''JG''. For separately payable drugs (status indicator ''K''), application of modifier ''JG'' will trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 22.5 percent. In response to the commenters' request that we allow the 340B modifier to be reported with status indicator ''N'' drugs (that is, drugs that are always packaged), we will accept modifier ''JG'' or ''TB'' to be reported with a packaged drug (although such modifier will not result in a payment adjustment).

In addition, beginning January 1, 2018, providers that are excepted from the 340B drug payment policy for CY 2018, which include rural SCHs, children's hospitals, and PPS-exempt cancer hospitals, should not report modifier ''JG''. Instead, these excepted providers should report the informational modifier ''TB'' (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier ''TB'' will facilitate the collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018. However, use of modifier ''TB'' will not trigger a payment adjustment and these providers will receive ASP+6 percent for separately payable drugs furnished in CY 2018, even if such drugs were acquired under the 340B Program.

For drugs administered to dual-eligible beneficiaries (that is, beneficiaries covered under both Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program, the State Medicaid programs should be aware of modifier ''JG'' to help further prevent inappropriate billing of manufacturer rebates.

With respect to comments about timing to operationalize a modifier, we note that hospitals have been on notice since the proposed rule went on display at the Office of the Federal Register on July 13, 2017 that we intended to establish a modifier to implement the policy for payment of drugs acquired under the 340B Program, if finalized. In addition, the modifier will not be required until January 1, 2018, which after display of this final rule with comment period will give hospitals two additional months to operationalize the modifier. Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. Therefore, for those hospitals that may need more time to ensure that they are in compliance with the modifier requirements, they have 12 months from the date of service to do so.

Further, to the extent many hospitals already report a modifier through their State Medicaid program, we believe that also requiring the modifier on outpatient claims for 340B-acquired drugs paid for under the OPPS would not be a significant administrative burden and would promote consistency between the two programs. With respect to providers in States that are not currently required to report a modifier under the Medicaid program, we note that providers are nonetheless responsible for ensuring that drugs are furnished to ''covered patients'' under the 340B Program and, therefore, should already have a tracking mechanism in place to ensure that they are in compliance with this requirement. Furthermore, modifiers are commonly used for payment purposes; in this case, the presence of the modifier will enable us to pay the applicable 340B drug rate of ASP minus 22.5 percent and track these claims in the Medicare data (in the case of ''JG'' modifier) and will allow us to track other drugs billed on claims that are not subject to the payment reduction (modifier ''TB''). In addition, the presence of the both modifiers will enable Medicare and other entities to conduct research on 340B-acquired drugs in the future.

We remind readers that our 340B payment policy applies to only OPPS separately payable drugs (status indicator ''K'') and does not apply to vaccines (status indicator ''L'' or ''M''), or drugs with transitional pass-through payment status (status indicator ''G'').

Finally, Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Medicare can also fine providers for knowingly, willfully, and repeatedly billing incorrectly coded claims. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

d. Summary of Final Policies for CY 2018

In summary, for CY 2018, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, separately payable Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in the section 1927(k) of the Act, that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at the ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). Medicare will continue to pay drugs that were not purchased with a 340B discount at ASP+6 percent.

Effective January 1, 2018, biosimilar biological products not on pass-through payment status that are purchased through the 340B program or through the 340B PVP will be paid at ASP minus 22.5 percent of the reference product's ASP, while biosimilar biological products on drug pass-through payment status will continue to be paid ASP+6 percent of the reference product.

To effectuate the payment adjustment for 340B-acquired drugs, CMS is implementing modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or those hospitals paid under the Maryland waiver) or excepted from the 340B drug payment policy for CY 2018, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final alternative 340B drug payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under

the OPPS for CY 2018. Specifically, the redistributed dollars will increase the conversion factor across non-drug rates by 3.2 percent for CY 2018.

We may revisit the alternative 340B drug payment methodology in CY 2019 rulemaking.

e. Comment Solicitation on Additional 340B Considerations

As discussed above, we recognize there are data limitations in estimating the average discount for 340B drugs. In the CY 2018 OPPS/ASC proposed rule (82 FR 33634 through 33635), we welcomed stakeholder input with regard to MedPAC's May 2015 analysis and the resulting estimate of ASP minus 22.5 percent as the proposed payment rate for separately payable, nonpass-through OPPS drugs purchased under the 340B Program in CY 2018. We also requested comment on whether we should adopt a different payment rate to account for the average minimum discount of OPPS drugs purchased under the 340B Program. Also, we sought comment on whether the proposal to pay ASP minus 22.5 percent for 340B-acquired drugs should be phased in over time (such as over a period of 2 to 3 years).

In addition, we recognize that the acquisition costs for drugs may vary among hospitals, depending on a number of factors such as size, patient volume, labor market area and case-mix. Accordingly, in the longer term, we are interested in exploring ways to more closely align the actual acquisition costs that hospitals incur rather than using an average minimum discounted rate that would apply uniformly across all 340B hospitals. In the proposed rule, we requested public comment on whether, as a longer term option, Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim. Having the acquisition cost on a drug-specific basis would enable us to pay a rate under the OPPS that is directly tied to the acquisition costs for each separately payable drug. To the extent that the acquisition costs for some drugs may equal the ceiling price for a drug, we recognize that there may be challenges with keeping the ceiling price confidential as required by section 1927(b)(3)(D) of the Act and we sought comment on this point.

Lastly, for consideration for future policy refinements, we requested public comment on (1) whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPPS (for example, rural SCHs or PPS-exempt cancer hospitals) if a policy were adopted to adjust OPPS payments to 340B participating hospitals (if so, describe how adjusted rates for drugs purchased under the 340B Program would disproportionately affect access in these provider settings); (2) whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment; and (3) whether hospital-owned or affiliated ASCs have access to 340B discounted drugs.

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: One commenter recommended that CMS establish an exemption mechanism for use by stakeholders to request exemptions for certain groups of hospitals. The commenters urged CMS to propose and seek comment on specific guidelines that outline procedures for stakeholders to request an exemption and the criteria CMS would use to determine whether to grant an exception.

Response: We appreciate the comment. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. For CY 2018, as stated earlier in this section, rural SCHs, children's hospitals and PPS-exempt cancer hospitals will be excepted from the alternative 340B drug payment methodology being adopted in this final rule with comment period. However, each of these excepted providers will report informational modifier ''TB'' on the same claim line as the HCPCS code for their 340B-acquired drugs.

Comment: In response to the solicitation of comments on whether CMS should exclude certain types of drugs from the proposed alternative 340B drug payment methodology, manufacturers of blood clotting factors and radiopharmaceuticals recommended that CMS continue to pay these drug types at ASP+6 percent. With respect to blood clotting factors, the commenters stated that individuals with bleeding disorders have unique needs and are expensive to treat such that the proposed reduced payment could threaten access and/or create unnecessary treatment delays for these patients. With respect to radiopharmaceuticals, the commenters stated that they do not believe that these products are covered outpatient drugs (because it is not possible for the manufacturer to accurately report final dose and pricing information), and therefore these drugs should be excluded as a category of drugs included in the covered drug definition for the 340B Program.

In addition, one commenter recommended that CMS develop a process for stakeholders to request exemptions from the alternative 340B payment methodology that CMS would evaluate using objective patient guidelines designed to ensure patient access.

Response: We appreciate the comments. To the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B Program, we believe that the OPPS payment rate for these drugs should account for the discounted rate under which they were purchased. Therefore, for CY 2018, OPPS payment for separately payable, nonpass-through drugs, biologicals, and radiopharmaceuticals, including blood clotting factors and radiopharmaceuticals, if purchased through the 340B Program, will be paid at ASP minus 22.5 percent. As we stated in the summary of final policies, we may revisit the 340B drug payment policy in the CY 2019 rulemaking. We will consider these requests for exceptions for certain drug classes in development of the CY 2019 OPPS/ASC proposed rule.

It is unclear to us whether the commenter meant that radiopharmaceuticals are not considered covered outpatient drugs under the OPPS or not considered a covered outpatient drug for purposes of the 340B Program. We assume the commenter was referring to the definition of covered outpatient drug for purposes of the 340B Program and, as such, these comments are outside the scope of the CY 2018 OPPS/ASC proposed rule. We refer commenters to HRSA with questions related to the 340B Program.

Comment: One commenter representing community oncology practices urged CMS not to ''reduce the size of the reimbursement reduction'' or to phase in the adjustment over 2 to 3 years because the commenter believed that hospitals would use that time to ''aggressively strong-arm independent community oncology practices to sell out to them.''

Response: As stated earlier in this section, we are finalizing our proposal to pay ASP minus 22.5 percent for separately payable nonpass-through drugs (other than vaccines). In addition, we agree that it is not necessary to phase in the payment reduction and are implementing the full adjustment for CY 2018.

Comment: Commenters expressed concern about the challenges and costs of implementing acquisition cost billing.

The commenters reported that hospital charge masters are not designed to bill drugs to one payer at a different rate than other payers. The commenters cited a survey response from hospitals that revealed acquisition cost billing would require investment in expensive software upgrades, obtaining a second charge master, or devising burdensome manual workarounds. One commenter stated that hospital cost reports already reflect the 340B acquisition cost based on expenses reported in the pharmacy cost center. The commenter further stated that these lower costs are already reflected in the drug CCR, which will likely be lower because the cost to acquire these drugs is lower. Thus, the commenter asserted, the OPPS ratesetting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition in the annual application of CCRs to pharmacy charges.

Response: We thank the commenters for their feedback and will take these comments into consideration for future policymaking. We note that several State Medicaid programs require reporting of actual acquisition cost (AAC) for 340B drugs so the magnitude of the challenges to implement may be less than the commenter suggests.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate prorata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2018 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2018. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2017 or beginning in CY 2018. The sum of the CY 2018 pass-through spending estimates for these two groups of device categories equals the total CY 2018 pass-through spending estimate for device categories with pass-through payment status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the CY 2018 OPPS/ASC proposed rule (82 FR 33635), we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2018, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2018 OPPS at ASP+6 percent, and because we proposed to pay for CY 2018 pass-through drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of the proposed rule, our estimate of drug and biological pass-through payment for CY 2018 for this group of items was $0, as discussed below. In the proposed rule, we noted that our estimate did not reflect the proposed payment policy for drugs purchased through the 340B program, as we discussed in section V.A. of the proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of the proposed rule and this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33635 through 33636), we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2018. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2018 was not $0, as discussed below. In section V.A.5. of the proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs

ability, presents the costs and benefits of this portion of this final rule with comment period. Table 89 and 90 of this final rule with comment period display the redistributive impact of the CY 2018 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

4. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule with comment period, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this final rule with comment period. In the CY 2018 OPPS/ASC proposed rule (82 FR 33711), we welcomed any comments on the approach in estimating the number of entities that will review the proposed rule. However, we did not receive any comments on our approach.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule with comment period, and therefore for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. In the CY 2018 OPPS/ASC proposed rule, we also sought public comments on this assumption, but we did not receive any comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this final rule with comment period. For each facility that reviews the rule, the estimated cost is $841.28 (8 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $2,851,939 ($841.28 × 3,390 reviewers).

5. Detailed Economic Analyses

a. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

(1) Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2018 policy changes on various hospital groups. We post on the CMS Web site our hospital-specific estimated payments for CY 2018 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. At the Web site, select ''regulations and notices'' from the left side of the page and then select ''CMS–1678–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 88 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters.

In the CY 2018 OPPS/ASC proposed rule, we solicited public comment and information about the anticipated effects of the proposed changes included in the proposed rule on providers and our methodology for estimating them. Any public comments that we receive are addressed in the applicable sections of this final rule with comment period that discuss the specific policies.

(2) Estimated Effects of OPPS Changes to Part B Drug Payment on 340B Eligible Hospitals Paid Under the OPPS

In section V.B.7. of this final rule with comment period, we discuss our finalized policies to reduce the payment for nonpass-through, separately payable drugs purchased by certain 340B-participating hospitals through the 340B Program. Rural SCHs, children's hospitals, and PPS-exempt cancer hospitals are excepted from this payment policy in CY 2018. Specifically, in this final rule with comment period, for CY 2018, for hospitals paid under the OPPS (other than those that are excepted for CY 2018), we are paying for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent instead of ASP+6 percent. For context, based on CY 2016 claims data, the total OPPS Part B drug payment is approximately $10.2 billion.

We recognize that it may be difficult to determine precisely what the impact on Medicare spending will be because OPPS claims data do not currently indicate if the drug being provided was purchased with a 340B discount. Furthermore, a list of outpatient drugs covered under the 340B program is not publicly available. Accordingly, for purposes of estimating the impact for this final rule with comment period, as we did in the CY 2018 OPPS/ASC proposed rule, we assumed that all applicable drugs purchased by hospitals eligible to participate in the 340B Program were purchased at a discounted price under the 340B program. While we recognize that certain newly covered entities do not have access to 340B drug pricing for designated orphan drugs, we believe that our CY 2018 policy to except newly covered entity types such as rural SCHs, PPS-exempt cancer hospitals, and children's hospitals, largely mitigates the 340B drug spend attributable to orphan drugs and therefore does not dramatically affect our final estimate. In addition, for this final rule with comment period, we utilized the HRSA covered entity database to identify 340B participating hospitals and cross-checked these providers with the CY 2018 OPPS facility impact public use file to determine which 340B hospitals are paid under the OPPS. The HRSA covered entity database is available via the Internet at *https://340bopais.hrsa.gov/coveredentitysearch*. Using this database, we found 1,338 OPPS hospitals in the 340B program (compared to the 954 estimated for the proposed rule). Of these, 270 were rural SCHs, 47 were children's hospitals, and 3 were PPS-exempt cancer hospitals. We did not assume changes in the quantity of 340B purchased drugs provided by hospitals participating in the 340B program (thereby affecting unit volume) or changes in the number of hospitals

participating in the 340B program that may occur due to the payment reduction.

While we acknowledge that there are some limitations in Medicare's ability to prospectively calculate a precise estimate for purposes of this final rule with comment period, we note that each hospital has the ability to calculate how this policy will change its Medicare payments for separately payable drugs in CY 2018. Specifically, each hospital that is not participating in the 340B program or that is excepted from the policy to pay for drugs acquired under the 340B Program at ASP minus 22.5 percent in CY 2018 will know that its Medicare payments for drugs will be unaffected by this finalized policy; whereas each hospital participating in the 340B Program has access to 340B ceiling prices (and subceiling prices if it participates in the Prime Vendor Program), knows the volume of 340B drugs that it has historically billed to Medicare, and can generally project the specific covered 340B drugs (and volume thereof) for which it expects to bill Medicare in CY 2018. Accordingly, a hospital participating in the 340B Program is able to estimate the difference in payment that it will receive if Medicare pays ASP minus 22.5 percent instead of ASP+6 percent for 340B drugs.

Using the list of participating 340B providers (derived from the HRSA database) and updated CY 2016 claims data available for this final rule with comment period for the applicable separately payable drugs and biologicals, excluding those on pass-through payment status and vaccines, billed by hospitals eligible to participate in the 340B Program, except for those hospital types that are excepted from this policy in CY 2018, we estimate that OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $1.6 billion under this finalized policy, which reflects an additional estimated reduction of $700 million over the proposed rule estimate of $900 million. If PPS-exempt cancer hospitals, children's hospitals, and rural SCHs had *not* been excluded from the reduced drug payment in CY 2018, drug payments to PPS-exempt cancer hospitals would have been reduced by approximately $29 million, to children's hospitals by approximately $2 million, and to rural SCHs by approximately $199 million—this would have resulted in a total savings estimate of approximately $1.8 billion. Because we are implementing this payment reduction in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.

Because data on drugs that are purchased with a 340B discount are not publicly available, we do not believe it is possible to more accurately estimate the amount of the aggregate payment reduction and the offsetting amount of the adjustment that is necessary to ensure budget neutrality through higher payment rates for other services. Furthermore, there are potential offsetting factors, including possible changes in provider behavior and overall market changes that would likely lower the impact of the payment reduction. As a result, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPPS, similar to the adjustment we made for clinical diagnostic laboratory test packaging policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70352 through 70357).

In this final rule, we project that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018. The estimated impacts of this policy are displayed in Table 88 below. We note that the payment rates included in Addendum A and Addendum B of this final rule with comment period do not reflect the reduced payments for drugs purchased under the 340B Program; however, they do include the increase to payments rates for non-drug items and services due to the corresponding increase in the conversion factor. In the proposed rule (82 FR 33712), we reminded commenters that this estimate could change in the final rule based on a number of factors, including other policies that are adopted in the final rule and the availability of updated data and/or method of assessing the impact in the final rule. We sought public comment on our estimate and stated that we were especially interested in whether commenters believe there are other publicly available data sources or proxies that can be used for determining which drugs billed by hospitals paid under the OPPS were acquired under the 340B Program.

We proposed that the reduced payments for separately payable drugs and biologicals purchased under the 340B Program would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget neutral weight scalar would not be applied in determining payments for these separately paid drugs and biologicals purchased under the 340B Program.

In addition, we solicited public comment on whether we should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, in CY 2018, rather than simply increasing the conversion factor. In particular, we sought public comment on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. Finally, we sought public comment on whether the redistribution of savings associated with the proposal would result in unnecessary increases in the volume of covered services paid under the OPPS that should be adjusted in accordance with section 1833(t)(2)(F) of the Act.

Comment: Several commenters stated that if the 340B drug payment policy was finalized, the funds should be redistributed across the OPPS, as has been the case for the application of budget neutrality in the past. One commenter supported CMS' proposal to implement the savings attributed to the 340B payment reduction in a budget neutral manner within the OPPS. Commenters noted that the budget neutrality requirement upon which CMS relied in the proposed rule at section 1833(t)(9)(B) of the Act has historically been interpreted by CMS as requiring budget neutrality within the OPPS. Commenters strongly urged CMS to follow its longstanding interpretation of section 1833(t)(9)(B) of the Act and offset the full amount of the aggregate 340B payment reduction through offsetting payment increases within the OPPS.

MedPAC reiterated its March 2016 recommendation that that payments be distributed in proportion to the amount of uncompensated care that hospitals provide, ''to make sure that dollars in the uncompensated care pool actually go to the hospitals providing the most uncompensated care.'' MedPAC commented that the 340B Program is not well targeted to hospitals that provide high levels of uncompensated care and noted that 40 percent of 340B hospitals provide less than the median level of uncompensated care. MedPAC stated that it believed that legislation would be needed to direct the savings to the uncompensated care pool because current law would require that the savings be retained within the OPPS to make it budget neutral. However,

MedPAC encouraged CMS to request that Congress enact the legislation necessary to allow CMS to implement its recommendation. MedPAC further noted that legislation would also allow CMS to apply the policy to all separately payable drugs, including those that are separately payable as a result of their pass-through status.

Response: We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal to fully redistribute the savings associated with adoption of the alternative payment methodology for drugs acquired under the 340B Program within the OPPS to non-drug items and services. That is, we will redistribute $1.6 billion dollars in estimated lower payment for OPPS drugs by increasing the conversion factor for all OPPS non-drug items and services by 3.2 percent. We may revisit how the funds should be targeted in the future.

Comment: Some commenters challenged the accuracy of the $900 million estimate CMS calculated in the proposed rule. According to these commenters, their analysis of the proposal would have an estimated impact in the range of $1.2 billion to $1.65 billion. As a result, these commenters asserted that if the proposed payment reductions are applied in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor, their analysis showed that payments for non-drug APCs would increase across hospitals by about 3.7 percent (in contrast to CMS's estimate of 1.4 percent) based on the proposed rule data. Moreover, based on their analysis, the commenters believed the redistribution of the savings would result in a net decrease in payments to 340B hospitals of approximately 2.6 percent, or approximately $800 million—funding that they stated was intended to support the congressionally-mandated mission of 340B hospitals—not be redistributed to other hospitals that do not participate in the 340B Program.

Response: We stated in the proposed rule that the estimate of the 340B payment reductions would likely change in the final rule based on updated data, revised assumptions, and final policies. For this final rule with comment period, as discussed in detail earlier, we used updated CY 2016 claims data and an updated list of 340B eligible providers to calculate an estimated impact of $1.6 billion based on the final policy. As shown in Table 88 below this reflects a reduction of about $1.5 billion to urban hospitals and $86 million to rural hospitals. We are redistributing the savings from this payment reduction in a budget neutral manner within the OPPS through an offsetting increase in the conversion factor. This increase to the conversion factor increases all OPPS non-drug payment rates to all providers under the OPPS by 3.2 percent. With respect to comments on the redistribution of the 340B savings to non-340B participating hospitals, we note that 340B hospitals will also receive the conversion factor increase.

Comment: In response to the comment solicitation on whether the savings generated by the reduced payment on 340B drugs should be used to increase payments for specific services paid under the OPPS or under Part B generally in CY 2018, commenters generally objected to the notion that CMS has authority to redistribute savings outside of OPPS. One commenter stated that CMS did not provide any analysis or justification to support a reading that section 1833(t)(9)(B) of the Act establishes a budget neutrality concept for the Medicare Part B Trust Fund. Another commenter stated that CMS should not redistribute the savings gained by the 340B proposal based on Medicare DSH metrics (that is, insured low-income days) because such metrics are not well correlated with uncompensated care costs. This commenter also expressed concern regarding the suitability of using uncompensated care as a metric ''to identify hospitals that provide the most help to needy patients because it includes bad debt as well as charity care.'' The commenter stated that bad debt is the amount that hospitals billed but did not collect, and therefore is not a measure of hospital assistance to the poor. Several commenters challenged the logic of reducing 340B payments to participating 340B hospitals, only to return the savings to the very same hospitals.

Response: We appreciate the feedback. Because the OPPS is a budget neutral payment system, historically CMS has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount. We have articulated the policy justification for reducing drug payment to ASP minus 22.5 percent for 340B-acquired drugs in section V.B.7. of this final rule with comment period and are redistributing the resulting dollars within the OPPS to maintain budget neutrality for CY 2018. Therefore, we are finalizing our proposal to redistribute the estimated reduction in payment for 340B-acquired drugs and biologicals by increasing the conversion factor, and we are not targeting the savings to specific services paid under the OPPS or under Part B generally. We continue to be interested in exploring ways that funds from a subsequent proposal could be targeted in future years to hospitals that serve a high share of low-income or uninsured patients.

Comment: Many commenters noted that CMS' proposal to redistribute the savings that result from the 340B reduction in a budget neutral manner within the OPPS would increase beneficiary copayments on non-drug services. Accordingly, the commenters stated that most patients would not directly receive the benefit of the 340B copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs. The commenters stated the proposal will likely increase costs for uninsured patients because 340B hospitals provide a disproportionate amount of care to that population and participating 340B hospitals may no longer be able to provide ''discounts to low-income patients'' or other uncompensated care. One commenter suggested that CMS, with stakeholder input, develop an outpatient hospital charity care metric that could be used to redistribute the 340B savings based on the level of outpatient charity care provided by the hospital.

Response: We appreciate the stakeholders' concerns. We believe that reducing payments on 340B purchased drugs to better align with hospital acquisition costs directly lowers drug costs for those beneficiaries who receive a covered outpatient drug from a 340B participating hospital. Further, to the extent that studies have found that 340B participating hospitals tend to use more high costs drugs, we believe that this 340B payment policy helps address drug pricing in the hospital outpatient setting by lessening the incentive for unnecessary utilization of costly drugs. In addition, even though many beneficiaries have supplemental coverage, those plans make coinsurance payments on behalf of beneficiaries. Thus, to the extent this policy lessens the coinsurance amount such supplemental plans would have to make, we would expect the price of such plans could decrease or otherwise reflect these lower costs in the future.

In summary, to maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the

OPPS through increasing the payment rates by 3.2 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018.

(3) Estimated Effects of OPPS Changes on Hospitals

Table 88 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We now include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2018, we are paying CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor as discussed in detail in section II.B. of this final rule with comment period. Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2018 is 2.7 percent (82 FR 38177). Section 1833(t)(3)(F)(i) of the Act reduces that 2.7 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.6 percentage point for FY 2018 (which is also the MFP adjustment for FY 2018 in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38177 through 38178)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the OPD fee schedule increase factor of 1.35 percent. We are using the OPD fee schedule increase factor of 1.35 percent in the calculation of the CY 2018 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2018 estimates in Table 88.

To illustrate the impact of the CY 2018 changes, our analysis begins with a baseline simulation model that uses the CY 2017 relative payment weights, the FY 2017 final IPPS wage indexes that include reclassifications, and the final CY 2017 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2018 over CY 2017 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2017 and CY 2018 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.35 percent OPD fee schedule increase factor update to the conversion factor; and the estimated impact taking into account all payments for CY 2018 relative to all payments for CY 2017, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2018. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2018 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2017 and CY 2018 by various groups of hospitals, which CMS cannot forecast.

In CY 2016, we excluded all molecular pathology laboratory tests from our packaging policy, and in CY 2017, we expanded the laboratory packaging exception to apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. For CY 2018, we sought public comments on whether laboratories (instead of hospitals) should be permitted to bill Medicare directly for molecular pathology tests and ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act (and are granted ADLT status by CMS), that are ordered less than 14 days following the date of a hospital outpatient's discharge from the hospital outpatient department.

The laboratory date of service (DOS) issue is discussed in section X.F. of this final rule with comment period. Because there are currently no laboratory tests designated as ADLTs and because the payment rate for laboratory tests excluded from our packaging policy billed by a hospital would have been the applicable rate for the laboratory test under the CLFS, any aspect of this discussion that is finalized in this final rule with comment period will not result in a net costs or savings to the program. Accordingly, section X.F. of this final rule with comment period is not included in the impact table in the regulatory impact analysis.

Overall, we estimate that the rates for CY 2018 will increase Medicare OPPS payments by an estimated 1.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.5 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,878), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2016 hospital outpatient and CMHC claims data to model CY 2017 and CY 2018 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2017 or CY 2018 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State

APPENDIX A

DESCRIPTION AND INTERESTS OF INDIVIDUAL *AMICI*

The Alabama Hospital Association (AlaHA), founded in 1921, is a statewide trade organization that assists member hospitals in effectively serving the health care needs of Alabama, through advocacy, representation, education and service. Members of the association include primarily hospitals and health systems, as well as other companies and organizations related to health care.

The Arkansas Hospital Association (ArHA) is a trade association representing over 100 hospitals and related institutions, and the more than 41,000 individuals employed by these organizations across the state of Arkansas. The ArHA is committed to improving the health of Arkansans through the delivery of high quality, efficient, and accessible health care for all. Serving a diverse population in a predominantly rural state, many Arkansas hospitals depend on the 340B Program to ensure that they can continue to provide and expand access to health care services to Arkansans, allowing them to receive the care they need close to home.

The California Hospital Association (CHA) is one of the largest hospital trade associations in the nation, serving more than 400 hospitals and health systems and 97 percent of the general acute care and psychiatric acute patient beds in California. CHA's members include all types of hospitals and health systems: non-profit; children's hospitals; those owned by various public entities, including cities/counties, local health care districts, the University of California, and the Department of Veterans Affairs; as well as investor-owned. The vision of CHA is an "optimally healthy society," and its goal is for every Californian to have equitable access to affordable, safe, high-quality, medically necessary health care. To help achieve this goal, CHA is committed to establishing and maintaining a financial and regulatory environment within which hospitals, health care systems, and other health care providers can offer high-quality patient care. CHA promotes its objectives, in part, by participating as *amicus curiae* in important cases like this one.

Colorado Hospital Association (CHA) represents more than 100 hospitals and health systems across the state. CHA's mission is to support its members' commitment to advance the health of their communities by delivering affordable, high-quality health care. Among other things, CHA serves its members by promoting initiatives to improve the quality, efficiency, and accessibility of health care provided by its constituent hospitals; promoting practices and legislation that best permit hospitals to improve their quality management and maintain the highest quality of service; and educating policymakers and other health care stakeholders on its member hospitals' perspectives involving important health care issues. CHA

takes interest in cases that have the potential to impact the operation and financial well-being of hospitals across the state.

The Georgia Hospital Association is a non-profit trade association made up of member hospitals and individuals in administrative and decision-making positions within those institutions. Founded in 1929, the Association serves 178 hospitals in Georgia. Its purpose is to promote the health and welfare of the public through the development of better hospital care for all of Georgia's citizens. The Association represents its members in legislative matters, as well as in filing *amicus curiae* briefs on matters of great gravity and importance to both the public and to health care providers serving Georgia citizens.

The Illinois Health and Hospital Association (IHA) is a statewide not-for-profit association with a membership of over 200 hospitals and nearly 50 health systems. For over 90 years, the IHA has served as a representative and advocate for its members, addressing the social, economic, political, and legal issues affecting the delivery of high-quality health care in Illinois. As the representative of virtually every hospital in the state, the IHA has a profound interest in this case. The IHA respectfully offers this *amicus curiae* brief in hopes of providing information not addressed by the litigants that will help the Court evaluate the litigants' arguments more thoroughly.

The Iowa Hospital Association (IHA) is a voluntary, not-for-profit membership organization representing all of Iowa's 118 community hospitals, including 82 critical access hospitals. IHA's mission is to support Iowa hospitals in achieving their mission and goals by advocating for member interests at the state and national level, and providing members with valuable education and information resources.

The Kansas Hospital Association (KHA) is a not-for-profit voluntary state organization located in Topeka, Kansas that represents and serves 127 community hospitals, including 85 Critical Access Hospitals. Its mission is to provide education and information and be the leading advocate for its members on the state and national level.

The Louisiana Hospital Association (LHA) is a non-profit organization founded in 1926 and incorporated in 1966 for the purpose of promoting the public welfare of the State of Louisiana. The Association's membership is composed of over 150 member institutions, with more than a thousand individual members. Membership consists of hospitals of all kinds, including public, private, non-profit, for-profit, federal, municipal, hospital service district, religious, general, specialty, acute-care, psychiatric, and rehabilitation classifications.

The Maine Hospital Association (MHA) represents all 36 community-governed hospitals in Maine including 33 non-profit general acute-care hospitals, two private psychiatric hospitals, and one acute rehabilitation hospital. In addition to acute care hospital facilities, it also represents 11 home health agencies, 18 skilled nursing facilities, 19 nursing facilities, 12 residential care facilities, and more than 300 physician practices. Its acute-care hospitals are non-profit, community-governed organizations with more than 800 volunteer community leaders serving on the boards of Maine's hospitals. Maine is one of only a handful of states in which all of its acute-care hospitals are non-profit.

The Massachusetts Health and Hospital Association (MHA) is a voluntary, not-for-profit organization composed of hospitals and health systems, related providers, and other members with a common interest in promoting the good health of the people of the Commonwealth of Massachusetts. Through leadership in public advocacy, education, and information, MHA represents and advocates for the collective interests of hospitals and health care providers, and it supports their efforts to provide high-quality, cost-effective, and accessible care.

Michigan Health & Hospital Association (MHA) is the statewide leader representing all community hospitals in Michigan. Established in 1919, the MHA represents the interests of its member hospitals and health systems in both the legislative and regulatory arenas on key issues and supports their efforts to provide quality, cost-effective and accessible care.

The Minnesota Hospital Association (MHA) is a Minnesota non-profit corporation that represents hospitals in the State of Minnesota, including 142 community-based hospitals and health systems and the physicians employed at those hospitals and health systems. MHA assists Minnesota hospitals in carrying out their responsibility to provide quality health care services to their communities; promote universal health care coverage, access, and value; and coordinate the development of innovative health care delivery systems. MHA serves it members and the State of Minnesota as a trusted leader in health care policy and as a valued source for health care information and knowledge.

The Mississippi Hospital Association (MHA) is a statewide trade association which serves the public by assisting its Members in the promotion of excellence in health through education, public information, advocacy, and service.

The Missouri Hospital Association (MHA) members include every acute-care hospital in the state, as well as most of the federal and state hospitals and rehabilitation and psychiatric care facilities. MHA actively serves its members'

needs through representation and advocacy on behalf of its members, continuing education programs on current health care topics, and education of the public and media as well as legislative representatives about health care issues.

The New Hampshire Hospital Association (NHHA) is the leading and respected voice for hospitals and health care delivery systems in New Hampshire, working together to deliver compassionate, accessible, high-quality, and financially sustainable health care to the patients and communities served by its member hospitals. NHHA represents 31 member hospitals, including a large academic medical center, 13 critical access hospitals, two specialty rehabilitation hospitals, one state psychiatric hospital, one private behavioral health hospital, and one VA Medical Center.

The New Jersey Hospital Association (NJHA) has served as New Jersey's premier health care association since its inception in 1918. NJHA currently has members across the health care continuum including hospitals, health systems, nursing homes, home health, hospice, and assisted living, all of which unite through NJHA to promote their common interests in providing quality, accessible and affordable health care in New Jersey. In furtherance of this mission, NJHA undertakes research and health care policy development initiatives, fosters public understanding of health care issues, and implements pilot programs designed to improve clinical outcomes and enhance patient safety. NJHA regularly appears before all three branches of government to provide the judiciary and elected and appointed decision makers with its expertise and viewpoint on issues and controversies involving hospitals and health systems.

The New Mexico Hospital Association (NMHA) is the trade association for acute-care hospitals in New Mexico. It advocates for the interests of its members at the state and federal level in the legislative and regulatory arenas. The NMHA represents 45 not-for-profit, investor-owned, and governmental hospitals and health systems from around the state.

The Healthcare Association of New York State (HANYS) is New York's statewide hospital and health system association representing over 500 not-for-profit and public hospitals and hospital based skilled nursing facilities, home health agencies, and hospices. HANYS' members range from rural Critical Access Hospitals to large, urban Academic Medical Centers and other Medicaid and safety net providers.

The Greater New York Hospital Association (GNYHA) is a Section 501(c)(6) organization that represents the interests of nearly 150 hospitals located throughout

New York State, New Jersey, Connecticut, and Rhode Island, all of which are not-for-profit, charitable organizations or publicly-sponsored institutions. GNYHA engages in advocacy, education, research, and extensive analysis of health care finance and reimbursement policy.

Pandion Healthcare Advocacy, Inc. is a nonprofit organization representing 17 hospitals across nine counties covering the Rochester and Finger Lakes region with a total of almost 5,000 beds. These hospitals include two teaching hospitals and serve a population of 1.3 million which makes up almost 12 percent of the state population (excluding New York City).

The Suburban Hospital Alliance of New York State is a consortium of 51 not-for-profit and public hospitals advocating for better health care policy for all those living and working in the nine counties north and east of New York City. The Suburban Alliance ensures that the specific concerns of suburban hospitals from the Hudson Valley and Long Island regions of New York are heard in Albany and Washington.

The Western New York Healthcare Association was founded in 1931 and is an industry association of health care providers in Erie, Niagara, Orleans, Genesee, Wyoming, Chautauqua, Cattaraugus, and Allegany counties, with member hospitals in rural to urban settings. The Association serves as a leading source of advocacy, policy, and health care information for its members and as an educator, communicator, and clearinghouse for health care information. While primarily focused on hospitals and affiliated nursing home providers, the Association also has non-hospital associate-level members.

The North Carolina Healthcare Association (NCHA) is a statewide trade association representing 136 hospitals and health systems in North Carolina, with the mission of uniting hospitals, health systems, and care providers for healthier communities. NCHA is an advocate before the legislative bodies, the courts, and administrative agencies on issues of interest to hospitals and health systems and the patients they serve.

The North Dakota Hospital Association (NDHA) has been representing hospitals and health-related member organizations for over 80 years. The NDHA is a voluntary, not-for-profit organization comprised of hospitals and health systems, related organizations, and other members with a common interest in promoting the health of the people of North Dakota.

The Ohio Hospital Association (OHA) is a private non-profit trade association established in 1915 as the first state-level hospital association in the United States. For decades the OHA has provided a forum for hospitals to come together to pursue health care policy and quality improvement opportunities in the best interest of hospitals and their communities. The OHA is comprised of 220 hospitals and 13 health systems, all located in Ohio, and works with its member hospitals across the state to improve the quality, safety, and affordability of health care for all Ohioans. The OHA's mission is to collaborate with member hospitals and health systems to ensure a healthy Ohio.

The Oregon Association of Hospitals and Health Systems (OAHHS), founded in 1934, is a statewide, non-profit trade association that works closely with local and national government leaders, business and citizen coalitions, and other professional health care organizations to enhance and promote community health and to continue improving Oregon's innovative health care community. Representing all 62 hospitals in Oregon, OAHHS provides leadership in health policy, advocacy, and comprehensive member services that strengthen the quality, viability, and capacity of Oregon hospitals to best serve their communities.

The Hospital and Healthsystem Association of Pennsylvania (HAP) is a statewide membership services organization that advocates for nearly 240 Pennsylvania acute and specialty care, primary care, subacute care, long-term care, home health, and hospice providers, as well as the patients and communities they serve.

The South Dakota Association of Healthcare Organizations (SDAHO) is the professional/trade association representing and serving health care organizations across the state in advancing healthy communities. The association has a not-for-profit mission and is funded principally through membership dues. Membership spans various types of category, geographic location, size and complexity of services and includes 54 hospitals, 3 health care systems, 32 nursing facilities, home health agencies, assisted living centers, and hospice organizations.

Tennessee Hospital Association (THA) was established in 1938 as a not-for-profit membership association to serve as an advocate for hospitals, health systems, and other health care organizations and the patients they serve. The Association also provides education and information for its members, and informs the public about hospitals and health care issues at the state and national levels.

The Texas Hospital Association (THA) is a non-profit trade association representing Texas hospitals. THA advocates for legislative, regulatory, and

judicial means to obtain accessible, cost-effective, high-quality health care. THA opposes reductions to 340B Program reimbursement that increase costs for uninsured or low-income patients and reduce hospitals' ability to provide expanded services to patients.

The Washington State Hospital Association (WSHA) is a non-profit membership organization that represents 107 member hospitals. WSHA works to improve the health of the people of the State by advocating on matters affecting the delivery, quality, accessibility, affordability, and continuity of health care.

The Vermont Association of Hospitals and Health Systems (VAHHS) is a statewide non-profit member organization comprised of Vermont's network of not-for-profit hospitals. Working with partners and stakeholders locally and nationally, VAHHS supports and contributes to policies that meet the association's core principles of making health care more affordable, maintaining high quality care, providing universal access, and preserving the individual's ability to choose their doctor and hospital. VAHHS is deeply committed to health care reforms and policies that help us achieve a vibrant, healthy Vermont.

The West Virginia Hospital Association (WVHA) is a not-for-profit statewide organization representing 63 hospitals and health systems across the continuum of care. The WVHA supports its members in achieving a strong, healthy West Virginia by providing leadership in health care advocacy, education, information, and technical assistance, and by being a catalyst for effective change through collaboration, consensus building, and a focus on desired outcomes.

The Wisconsin Hospital Association (WHA) is a statewide non-profit association with a membership of more than 130 Wisconsin hospitals and health systems. For nearly 100 years, the Wisconsin Hospital Association has advocated for the ability of its members to lead in the provision of high-quality, affordable, and accessible health care services, resulting in healthier Wisconsin communities.