[ORAL ARGUMENT NOT SCHEDULED]

No. 17-5018

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

AMERICAN HOSPITAL ASSOCIATION; BAXTER REGIONAL HOSPITAL, INC., d/b/a BAXTER REGIONAL MEDICAL CENTER; RUTLAND HOSPITAL, INC., d/b/a RUTLAND REGIONAL MEDICAL CENTER; COVENANT HEALTH,

Plaintiffs-Appellees,

v.

THOMAS E. PRICE, M.D., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR THE APPELLANT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. *Parties and Amici.* The following parties appeared in district court and are parties before this Court now:

Plaintiffs-Appellees are American Hospital Association; Baxter Regional Hospital, Inc., d/b/a Baxter Regional Medical Center; Rutland Hospital, Inc., d/b/a Rutland Regional Medical Center; and Covenant Health.

Defendant-Appellant is Thomas E. Price, M.D., in his official capacity as Secretary, U.S. Department of Health and Human Services. Former Secretaries and Acting Secretaries of Health & Human Services Norris W. Cochran, Kathleen Sebelius, and Sylvia M. Burwell were previously named as defendants in their official capacities.

The following participated as amicus supporting plaintiffs in both the district court and in the prior appeal:

Fund for Access to Inpatient Rehabilitation.

B. *Rulings Under Review.* Defendant appeals from the memorandum opinion and order issued on December 5, 2016, by the Honorable James E. Boasberg, Dkt. Nos. 47, 48, No. 1:14-cv-851 (D.D.C.) (Mem. Op. at 2016 WL 7076983), and the interlocutory rulings by Judge Boasberg upon which that final judgment was predicated, including the order and memorandum opinion issued on September 19, 2016, denying defendant's motion for a stay, Dkt. Nos. 37, 38 (Mem. Op. at 2016 WL

5106997). Defendant also appeals from Judge Boasberg's order of January 4, 2017, which denied reconsideration, Dkt. No. 52.

C. *Related Cases*. This case was previously before this Court in *American Hospital Association v. Burwell*, No. 15-5015, which was decided on Feb. 9, 2016. *See* 812 F.3d 183. Defendant is aware of one currently pending case that is related within the meaning of D.C. Cir. R. 28(a)(1)(C): Substantially the same issues are presented in *Casa Colina Hospital & Centers For Healthcare v. Burwell*, No. 15-56725 (9th Cir.), which is fully briefed and awaiting argument.

/s/ *Joshua Salzman*
Joshua M. Salzman

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GLOSSARY

ALJ	Administrative Law Judge
HHS	U.S. Department of Health and Human Services
OMHA	Office of Medicare Hearings and Appeals
RAC	Recovery Audit Contractor

INTRODUCTION

The district court ordered the Department of Health and Human Services (HHS) to eliminate a backlog of over 650,000 appeals of denied Medicare claims currently pending before Administrative Law Judges (ALJs). The order establishes a series of dates for percentage reductions, mandating a 30% reduction of the backlog by the close of 2017, and total elimination of the backlog by the end of 2020. HHS cannot lawfully comply with this order.

HHS's Office of Medicare Hearings and Appeals (OMHA), which administers the nationwide Medicare ALJ hearing program, is funded by a line-item appropriation. It is not controverted that eliminating the backlog is OMHA's priority, that OMHA has used all the funds at its disposal to do so, and that HHS has taken a series of administrative measures that has significantly reduced the number of pending cases. It is not controverted that HHS has repeatedly and unsuccessfully sought substantial funding increases and new authorities from Congress. And it is not controverted that, absent increased funding and new authorities, the agency cannot meet any part of the district court's schedule unless it settles vast numbers of claims without regard to their merit, thereby abdicating its statutory responsibilities and paying claims never authorized by Congress. The agency fully explained these circumstances to the district court, and the court did not explain how the agency could meet the court-imposed deadlines and also fulfill its statutory duties.

The district court erred as a matter of law and abused its equitable discretion by nevertheless dictating a timetable for the disposition of appeals. No principle of law authorizes a district court to employ its equitable powers to effectively require settlement of claims regardless of their merit. And, as the agency explained, the practical consequences of the order are sweeping. The combined billed amounts of the outstanding claims total approximately $6.6 billion. JA170. Based on the 2016 success rate of providers in ALJ hearings, the agency expects that less than 30% of the appealed claims in the backlog meet statutory requirements for payment and are not otherwise procedurally flawed so as to preclude payment. *Id.* The court's order thus effectively requires payment of hundreds of millions of dollars never authorized by Congress, in contravention of established law.

In a prior decision in this case, *American Hospital Association v. Burwell*, 812 F.3d 183 (D.C. Cir. 2016), this Court held that HHS is in violation of a statutory directive requiring that the agency complete ALJ review within ninety days. The Court remanded for the district court to determine whether plaintiffs could show as an equitable matter that the agency's continuing failure to meet the ninety-day timeline was a basis for mandamus relief, declaring that the agency could not allow "discretionary" programmatic decisions to frustrate a timely hearings process. *Id.* at 193. Remand proceedings have established that the backlog is not a product of the Secretary's discretionary programmatic decisions, but is rather the inevitable consequence of Congress's appropriation decisions. Because the "problem stem[s]

from a lack of resources," it is "'a problem for the political branches to work out.'" *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1101 (D.C. Cir. 2003) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 75 (D.C. Cir. 1991)). As the Fourth Circuit concluded in addressing the same claims presented here, to the extent "the backlog [is] attributable to Congress' failure to fund the program more fully or otherwise to provide a legislative solution, it . . . [is] a problem for Congress, not the courts, to address." *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016). Accordingly, we respectfully urge that the district court erred in issuing any mandamus order and even more clearly erred in establishing a timetable for the disposition of appeals.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction pursuant to 28 U.S.C. § 1361. JA16. The district court granted plaintiffs' motion for summary judgment on December 5, 2016. JA160. The Secretary filed a timely motion for reconsideration, which was denied on January 4, 2017. JA172-JA174. The Secretary filed a timely notice of appeal on January 30, 2017. JA175. This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1291.

STATUTES AND REGULATIONS

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

STATEMENT OF THE ISSUE

Whether the district court erred in ordering HHS to resolve appeals involving outstanding reimbursement claims by Medicare providers totaling over $6.6 billion on a court-established schedule, even though the backlog results from inadequate congressional appropriations, and even though the agency cannot meet the court's schedule without violating its statutory obligation to pay only meritorious claims.

STATEMENT OF THE CASE

A. Medicare And The Administrative Appeals Process For Part A And Part B Claims

1. Medicare is a federal program of health insurance for the elderly and disabled. In general, Part A covers inpatient hospital stays and other institutional care, as well as home health care, *see* 42 U.S.C. § 1395d, and Part B covers physician and other medical services, *see id.* § 1395k. Congress has imposed a variety of restrictions on the Secretary's authority to pay for specified products and services, *see generally id.* § 1395y(a), and has also established conditions for provider eligibility and conditions to be satisfied before payment may issue, *see, e.g., id.* § 1395f (Medicare Part A); *see also id.* § 1395n (Part B).

2. This case concerns the administrative process for resolving claims for reimbursement by providers of Medicare services. The Medicare program processes more than 1.2 billion individual benefit fee-for-service claims each year. JA90. This payment process begins when a provider submits claims to a Medicare Administrative

Contractor, a private contractor responsible for making an "initial determination" as to what payment (if any) should be made on a claim. *See* 42 U.S.C. § 1395kk-1(a); *id.* § 1395ff(a)(1)-(2). In the event that a claim is denied, a provider can pursue four levels of administrative appeal and then judicial review. *See id.* § 1395ff. The first level of review is provided by an adjudicator at the Medicare Administrative Contractor who was not involved in the initial determination, and the second level is provided by a separate independent contractor *See id.* § 1395ff(a)(3), (b)-(c), (g). A significant number of disputes are resolved at these first two levels of appeal. *See, e.g.*, JA147.

A provider who continues to be dissatisfied with the resolution of its claim may then seek a hearing before an ALJ. 42 U.S.C. § 1395ff(b), (d)(1). The Medicare statute provides that ALJs "shall conduct and conclude a hearing on a decision of [the contractor that provides the second level of review] and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." *Id.* § 1395ff(d)(1)(A).

The statute specifies the "[c]onsequences of failure to meet [this] deadline[]"; if the ALJ fails to provide a timely determination, the party is excused from having to exhaust ALJ review and may "escalate" the appeal—without an ALJ hearing decision—to the Medicare Appeals Council, a component within HHS's Departmental Appeals Board that provides final administrative review of reimbursement appeals. 42 U.S.C. § 1395ff(d)(2), (3). The Medicare Appeals Council

conducts de novo review, *id.* § 1395ff(d)(2)(B), and its decisions are subject to judicial review, *id.* § 1395ff(b)(1)(A).

The ALJ hearing program is administered by OMHA, which is an independent division within the Office of the Secretary of HHS. *See* JA84; *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, § 931, 117 Stat. 2066, 2396 (2003) (Modernization Act); 76 Fed. Reg. 19,995 (Apr. 11, 2011); 70 Fed. Reg. 36,386 (June 23, 2005). To help maintain the independence of the office, Congress funds OMHA through a separate line item appropriation. JA84; Consolidated Appropriations Act, 2016, Pub. L. No. 114–113, div. H, tit. II, 129 Stat. 2242, 2618 (2015).[1]

B. The Recovery Audit Contractor Program

In 2003, Congress directed the Secretary to "conduct a demonstration project . . . to demonstrate the use of recovery audit contractors" to identify and recoup overpayments under Medicare parts A and B. Modernization Act, § 306, 117 Stat. at 2256. Congress instructed the Secretary to hire independent contractors to identify duplicative payments, inaccurate coding, and other breaches of payment policies in which inaccurate payments arise. *Id.*

[1] Congress generally extended fiscal year 2016 appropriations until April 28, 2017. *See* Continuing Appropriations Act, 2017, Pub. L. No. 114–223, div. C, 130 Stat. 857, 909 (2016), as extended by Pub. L. No. 114–254, div. A, § 101, 130 Stat. 1005, 1005 (2016).

"In light of the demonstration project's success, Congress made the [recovery audit contractor] program a permanent part of the Medicare Integrity Program and expanded its coverage to all states." *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1157 (9th Cir. 2012); *see* Pub. L. No. 109–432, div. B, § 302, 120 Stat. 2922, 2991 (2006) (codified at 42 U.S.C. § 1395ddd(h)). The recovery audit contractor (RAC) program took nationwide effect in 2010. 42 U.S.C. § 1395ddd(h)(1). It has since recovered billions of dollars in wrongful payments.

Under the RAC program, auditors review claims that have already been paid to determine, among other things, if those claims were paid improperly. If a RAC flags a claim as having been paid improperly, the provider can repay the challenged amount or may obtain review through the four-level administrative appeal process described above. While the RAC program is statutorily required, many implementation details are delegated to the Secretary. As this Court noted in the prior appeal, the Secretary has some discretion to limit the scope of the audits conducted under this program. *See American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 193 (D.C. Cir. 2016) (*AHA*).

The RAC program was, at one time, a major (though by no means exclusive) generator of appeals reaching OMHA. But over the course of the litigation, and in significant part in direct response to the backlog at issue, HHS made several changes to the program. These changes have decreased the number of RAC-identified claims

that enter the Medicare appeals system (JA96), and the number of RAC-related appeals reaching OMHA has "decreased drastically." JA140; *see also* JA157.[2]

C. The Present Backlog Of Provider Medicare Appeals

The ninety-day time frame for the third level of Medicare appeals took effect in 2005. In general, the agency successfully met that time frame from its inception through fiscal year 2010. JA84. Starting in 2010, the upward trend in ALJ hearing requests "took an unexpectedly sharp turn." *Id.* Between fiscal years 2011 and 2013 alone, appeals filed with the agency surged by 545%. *Id.* A combination of factors contributed to this dramatic workload increase, including increased use of Medicare-covered services by an aging population; the additional appeals from audits conducted under the RAC program; and increases in Medicaid state agency appeals of Medicare coverage denials for beneficiaries enrolled in both Medicare and Medicaid. JA91-JA94. Between 2010 and 2015, the agency experienced a 316% increase in "traditional," non-RAC appeals. JA92.

Despite the massive increase in its workload, Congress provided OMHA with only a modest increase in funding. JA85; *see also* OMHA, HHS, *Fiscal Year 2017*

[2] These changes have had a corresponding effect on the RAC program's ability to recover improperly paid funds. In fiscal year 2015, the amount of money returned to the Medicare Trust Funds by the RAC program was $141 million, down 91% from the $1.6 billion returned in fiscal year 2014. *See* Centers for Medicare & Medicaid Services, HHS, *Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015*, at v, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY2015-Medicare-FFS-RAC-Report-to-Congress.pdf.

Justification of Estimates for Appropriations Committee 13 (*FY 2017 Budget Estimate*) (showing essentially flat appropriations between 2010 and 2013 and limited increases since).[3] HHS restructured staffing in a way that enabled the average number of dispositions per ALJ to double between fiscal year 2009 and fiscal 2013, but OMHA was nonetheless overwhelmed by its new workload. JA84. In fiscal year 2014, OMHA received nearly 475,000 appeals and was able to resolve only 87,000. JA156. By July 2014, the resulting backlog exceeded 800,000 appeals. JA85.[4]

HHS "has made it a priority to adopt measures that are designed to reduce that backlog" (JA89), and as a result of its efforts, the backlog had been reduced to about 658,000 appeals as of December 2016 (JA168). For example, HHS identified a large class of homogeneous appeals related to a certain type of inpatient hospital claim denial, where the only issue was the amount owed, and globally settled those claims, thereby removing some 380,000 claims from the backlog. JA141-JA142. HHS has undertaken other initiatives to reduce the number of incoming appeals as well as the number of claims in the backlog, including settlement facilitation and programs to

[3] http://www.hhs.gov/sites/default/files/fy2017-budget-justification-office-of-medicare-hearings-and-appeals_0.pdf (last visited Feb. 21, 2017).

[4] The Departmental Appeals Board, which provides the fourth level of review through the Medicare Appeals Council, has likewise seen a surge in the number of appeals, and has developed its own (smaller) backlog. While this litigation initially involved a challenge to this backlog as well (JA32), the mandamus order at issue addresses only the OMHA backlog.

allow providers with many appeals to resolve claims using statistical sampling and extrapolation. *See generally* JA95-JA100.

Nevertheless, as of March 2016, OMHA was receiving approximately 3,500 new appeals per week (roughly 180,000 annually). JA91; *see also* JA156 (agency projections of future appeals). With funding at the Fiscal Year 2017 Continuing Resolution level, however, OMHA can adjudicate only about half that amount. JA156 (projecting that continuation of current Fiscal Year 2017 funding will allow disposition of 92,000 appeals).

HHS has repeatedly asked Congress for significant increases to OMHA's budget, as well as congressional approval for new authorities that would allow OMHA to process a greater number of appeals and facilitate the appropriate resolution of appeals at earlier levels of the process. *See, e.g.*, *FY 2017 Budget Estimate* at 7; *Statement of Nancy J. Griswold Before the United States Senate Finance Committee* 7-9 (Apr. 28, 2015).[5] Both Houses of Congress have conducted hearings on the issue,[6] and members of Congress from both sides of the aisle have recognized that OMHA currently lacks the resources and authorities needed to resolve the backlog. *See, e.g.*, *Wyden Statement at*

[5] https://www.finance.senate.gov/imo/media/doc/SFC%20Griswold-OMHA%20updated%20testimony%20%204%2028%2015.pdf.

[6] *See Medicare Mismanagement Part II: Exploring Medicare Appeals Reform: Hearing Before the Subcomm. on Energy Policy, Health Care, and Entitlements, of the H. Comm. on Oversight & Government Reform*, 113th Cong. (2014); *Creating a More Efficient and Level Playing Field: Audit and Appeals Issues in Medicare: Hearing Before Sen. Comm. on Finance*, 114th Cong. (2015).

Finance Hearing on the Medicare Appeals Process (Apr. 28, 2015) ("with a 10-fold increase in the number of cases, it's clear that additional resources are needed");[7] *Hatch Statement at Finance Hearing on Medicare Audit and Appeals* (Apr. 28, 2015) ("The Office of Medicare Hearings and Appeals has . . . taken steps to address its backlog, but there is only so much the agency can do with their current authorities and staffing.").[8] In June 2015, the Senate Finance Committee unanimously reported out a bipartisan bill, the Audit & Appeals Fairness, Integrity, and Reforms in Medicare Act of 2015, to address existing problems in the Medicare appeals process, including the existing backlog, and to provide OMHA with a significant funding increase. *See* S. 2368, 114th Cong. (2015); *see also* S. Rep. No. 114–177 (2015). However, the legislation did not proceed further.

D. Facts And Prior Proceedings

1. Plaintiffs are the American Hospital Association and three individual hospitals or health systems that state they have appeals that have been pending before OMHA for more than ninety days. JA14-JA16. In 2014, they filed this suit pursuant to 28 U.S.C. § 1361, seeking, as relevant here, a mandamus order to compel the Secretary to provide ALJ hearings within ninety days. JA30-JA32.

[7] https://www.finance.senate.gov/ranking-members-news/wyden-statement-at-finance-hearing-on-the-medicare-appeals-process.

[8] https://www.finance.senate.gov/chairmans-news/hatch-statement-at-finance-hearing-on-medicare-audit-and-appeals.

The district court initially granted the agency's motion to dismiss. *See American Hosp. Ass'n v. Burwell*, 76 F. Supp. 3d 43 (D.D.C. 2014). Recognizing that "OMHA has been saddled with a workload it cannot, at present, possibly manage" and that "Congress is well aware of the problem," the court held that because the agency "is underfunded" and "processing Plaintiffs' appeals on a first-come, first-served basis," the court should not intervene. *Id.* at 55.

2. A panel of this Court reversed and vacated. *See AHA*, 812 F.3d at 194. The panel concluded that the failure to provide ALJ hearings within ninety days constituted a statutory violation, and, noting that the backlog had worsened in the year since the district court's ruling, directed the district court to reweigh the equities in light of changed circumstances. *Id.* at 192. To guide the district court's analysis, this Court highlighted several factors weighing for and against issuance of the writ. The factors against mandamus included the writ's "extraordinary and intrusive nature, which risks infringing on the authority and discretion of the executive branch." *Id.* The Court also highlighted the agency's good-faith efforts to reduce the delays within existing constraints, the availability of escalation as an alternative means for providers to escape the backlog, and Congress's awareness of the problem. *Id.* at 192-93. The Court emphasized that the "backlog and delays have their origin in the political branches, and ideally the political branches should resolve them." *Id.* at 193.

The Court also pointed to factors that would weigh in favor of mandamus. These included the substantial harm the Court found plaintiffs experienced from

waiting years to obtain reimbursements. *AHA*, 812 F.3d at 193. The Court also focused on the RAC program's contributions to the backlog. The Court explained that "critically to [its] thinking about this case, although Congress directed the Secretary to establish the RAC program, it has left [the Secretary] with substantial discretion to implement it and determine its scope," and that "congressionally imposed mandates and prohibitions trump discretionary decisions." *Id.* Other than curtailing the RAC program, the Court did not identify any mechanism through which the Secretary might alleviate or eliminate the backlog. *Id.* at 192-93.

The Court did not prejudge whether mandamus should issue, leaving it to the district court to weigh the equities in the first instance. *AHA*, 812 F.3d at 192-93. The Court did suggest, however, that "the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle." *Id.* at 193.

3. On remand, HHS moved for a stay of proceedings until September 2017 (*i.e.*, the close of the next full appropriations cycle). JA115. In support of that motion, HHS provided a declaration detailing the extensive steps that HHS was taking to address the backlog, including reforms to the RAC program, and demonstrating how, if Congress approved new resources, the backlog could be eliminated by 2021. *See generally* JA88-JA113.

The district court denied the stay motion. In so doing, the district court concluded that the stay and underlying mandamus inquiries are "overlapping" (JA121), and thus, its decision required consideration of the mandamus merits. Citing the new HHS declaration, the district court recognized that "the Secretary appears to have devoted considerable effort to designing and implementing various administrative initiatives to target the backlog." *Id.* The court viewed these measures as inadequate, however, because unless they were coupled with additional funding, they would merely slow the growth of the backlog, not yield any progress towards its resolution. JA127. As for the prospect of new funding, the court noted that no hearings were being held on the proposed legislation to address the backlog and concluded that "Congress is unlikely to play the role of the cavalry here, riding to the rescue of the Secretary's besieged program." JA130. The court concluded that the "balance of interests drives the conclusion that there are equitable grounds for mandamus," and asked the parties for additional submissions. *Id.*

After additional briefing, and on consideration of cross-motions for summary judgment, the district court granted plaintiffs' motion and issued the writ. Adopting a timetable proposed by plaintiffs, the court ordered the Secretary to achieve the following reductions from the current backlog of cases pending at the ALJ level: 30% by December 31, 2017; 60% by December 31, 2018; 90% by December 31, 2019; and 100% by December 31, 2020. JA166. The court rejected plaintiffs' suggestion that HHS be deemed to have defaulted on all backlogged claims as of January 1, 2021, and

stated instead that if the Secretary fails to meet the above deadlines, plaintiffs may move for default judgment or to otherwise enforce the writ of mandamus. *Id.* The court also ordered the Secretary to file status reports at ninety-day intervals. JA167.

HHS moved for reconsideration, which was denied. JA172-JA174. This timely appeal followed.

SUMMARY OF ARGUMENT

The district court ordered HHS to resolve a backlog of administrative appeals where the agency lacks the resources and authorities that would be necessary to do so in a lawful manner. The backlog is a direct consequence of congressional appropriations decisions and not, as this Court assumed in a prior appeal, "discretionary" programmatic decisions by HHS, *American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 193 (D.C. Cir. 2016). Because the agency is already making good-faith efforts to address the backlog within existing constraints and the obstacle to resolution is a funding shortfall, mandamus should not have issued.

Even if some form of mandamus relief were appropriate—and it is not—the district court still erred in its choice of remedy. Given OMHA's limited adjudication capacity, HHS cannot possibly comply with an order requiring it to eliminate the backlog unless it pays or settles claims en masse, without regard to the merits of the claims settled. Such settlements would contravene strict payment criteria imposed by Congress and require the expenditure of amounts far above what Congress has authorized. The district court erred in effectively requiring HHS to pay hundreds of

millions of dollars to resolve claims that three prior adjudicators have already concluded cannot lawfully be paid, and which fail at the ALJ level in more than 70% of cases. JA170. Any mandamus relief must be limited to measures consistent with statutory requirements.

STANDARD OF REVIEW

This Court reviews the equities of whether mandamus should issue for abuse of discretion. *See American Hosp. Ass'n v. Burwell*, 812 F.3d 183, 190 (D.C. Cir. 2016). "A district court by definition abuses its discretion when it makes an error of law." *Koon v. United States*, 518 U.S. 81, 100 (1996). The Court reviews denials of motions for reconsideration under Federal Rule of Civil Procedure 59(e) for abuse of discretion. *Anyanwutaku v. Moore*, 151 F.3d 1053, 1058 (D.C. Cir. 1998).

ARGUMENT

THE COURT SHOULD REVERSE THE MANDAMUS ORDER AND DIRECT ENTRY OF JUDGMENT IN FAVOR OF THE SECRETARY

A. Mandamus Should Not Have Issued Because The Agency Has Taken All Steps Within Its Power To Reduce The Administrative Backlog, Which Does Not Result From Discretionary Choices Regarding The Recovery Audit Contractor Program

1. In the prior appeal in this case, this Court held that the agency is in violation of a statutory duty to provide ALJ hearings within ninety days. *See American Hosp.*

Ass'n v. Burwell, 812 F.3d 183, 192 (D.C. Cir. 2016) (*AHA*).[9] The Court did not undertake the task of determining whether a writ of mandamus should issue or what relief would be appropriate. The Court invited a political resolution, noting that its decision might prompt Congress to "'clarify' potentially conflicting signals." *Id.* at 194; *see also id.* at 192-93 ("The backlog and delays have their origin in the political branches, and ideally the political branches should resolve them."); Oral Arg. Recording at 47:47 (Tatel, J.) ("Wouldn't it help the Secretary in terms of her effort to get more resources to have a little pressure from the courts" through an order "short of mandamus"?).[10] Thus, while the Court suggested that "the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle," *AHA*, 812 F.3d at 193, it did not, of course, purport to determine whether and what relief might be appropriate in that circumstance.

The Court's decision also reflected an assumption that HHS could make discretionary decisions in the operation of the RAC audit program that would significantly reduce its efficacy, but would substantially eliminate the backlog of

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[9] The Fourth Circuit subsequently reached a contrary conclusion, holding that mandamus is not available to compel compliance with the timetable for Medicare appeals. *See Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 55 (4th Cir. 2016). While we recognize that the prior panel's ruling is binding on this Court at the panel stage, the Secretary reserves the right to challenge that holding on further review.

[10] Available at https://www.cadc.uscourts.gov/recordings/recordings.nsf/DocsByRDate?OpenView&count=100&SKey=201511.

administrative appeals, noting that it was "critical[]" to its thinking about the case that Congress had given the agency substantial discretion to determine the RAC program's scope. *AHA*, 812 F.3d at 193; *see id.* at 185 (describing the "heart" of the case as a conflict between the ninety-day timetable and the RAC program); *id.* at 187 (describing "the backlog and its connection to the RAC program"); *id.* at 192 (describing a potential mandamus order as "drastically limiting the scope of a statutorily mandated program that has recovered billions of dollars in incorrectly paid funds"); *id.* at 193 (similar).

The record on remand demonstrates, however, that curtailment of the RAC program cannot resolve the backlog. Since this litigation commenced, the agency has made significant changes to the RAC program and the number of RAC-related appeals reaching OMHA has "decreased drastically." JA140; *see* JA157. In 2013 and 2014, more than 50% of all new OMHA appeals were RAC-related, and over those two years, the RAC program was responsible for more than 450,000 appeals. JA140; *see also AHA*, 812 F.3d at 187 (noting that at the time of the November 2015 oral argument, 46% of the backlogged appeals were RAC-related). In 2015, by contrast, RAC appeals comprised just 14.1% of new appeals to OMHA, and in 2016, this figure fell to 9.5% (fewer than 16,000 appeals). JA140.[11]

[11] Although these reductions are partially attributable to a temporary decrease in RAC activity, several changes are expected to have a lasting and significant effect on RAC receipts. JA140-JA141.

The 16,000 RAC-related appeals received in 2016 represent just 2.5% of the total backlog and limiting that inflow would not appreciably improve the backlog. Even if the number of new incoming RAC appeals were reduced to zero, OMHA would continue to receive roughly twice as many appeals as it has capacity to adjudicate. *See* JA91; JA156. Thus, the backlog cannot be resolved by applying the rule that "congressionally imposed mandates and prohibitions trump discretionary decisions," *AHA*, 812 F.3d at 193, even assuming that the Secretary has the discretion to strip the RAC program of all efficacy.

2. Nor are there other discretionary measures that HHS could take to eliminate the backlog. The financial and legal restrictions that prevent HHS from resolving the backlog are statutory.

OMHA is funded through a line-item appropriation and the Secretary has no meaningful authority to augment OMHA's funding. *See* Consolidated Appropriations Act, 2016, div. H, tit. II, 129 Stat. at 2618; *id.* § 205, 129 Stat. at 2619 (Secretary cannot augment any appropriation by more than 3%). HHS is also constrained in its ability to increase the adjudicative capacity of the ALJs whom Congress has chosen to fund. ALJs' decision-making duties are prescribed by statute, and the Medicare statute generally requires that ALJs provide a "hearing," and then issue a written decision stating "the specific reasons for the determination." 42 U.S.C. § 1395ff(b)(1)(A), (d)(4)(A). OMHA has already added support staff to maximize the productivity of its ALJs, doubling their disposition capacity. JA84-JA85. HHS has

also proposed hiring "attorney adjudicators" to handle appeals in the subset of cases where regulations allow resolution of an appeal without a hearing. *See* 82 Fed. Reg. 4974, 4981-89 (Jan. 17, 2017). Any further efforts to decrease the amount of ALJ time spent per appeal would have a significant impact on the quality of the decisions being issued.

HHS also has a statutory obligation to ensure that non-meritorious claims are not paid. "Notwithstanding any other provision" of the Medicare statute—including the provision imposing the ninety-day timeline for ALJ hearings— "no payment may be made . . . for any expenses incurred for items or services" that do not meet statutory criteria. 42 U.S.C. § 1395y(a). Likewise, claims can only be paid where "[c]onditions of and limitations on payment for services" are satisfied, *id.* § 1395f (Medicare Part A); *see also id.* § 1395n (similar restrictions under Part B), and where the amounts due have been sufficiently verified, *id.* §§ 1395g(a) (Medicare Part A), 1395*l*(e) (Medicare Part B). The agency is also charged with maintaining program integrity against waste, fraud, and abuse. *Id.* § 1395ddd. The Medicare statute thus bars the agency from addressing the backlog through measures that would either require payment of claims that do not meet statutory criteria for payment or degrade the process of claim verification.

3. This Court recognized in the prior appeal that the agency had made "good faith efforts to reduce the delays within the constraints [it] faces—such as by implementing reforms that have doubled ALJ efficiency." *AHA*, 812 F.3d at 192.

And the district court on remand acknowledged that throughout the pendency of this litigation, the Secretary has "devoted considerable effort to designing and implementing various administrative initiatives to target the backlog." JA121.

Indeed, HHS "has made it a priority to adopt measures that are designed to reduce th[e] backlog." JA89. These include programs to encourage merits-based settlements, expedited resolution of claims, and a variety of other proposals designed to limit the number of disputes that reach OMHA and to resolve those that get there more quickly. *See generally* JA95-JA105; *see also* 82 Fed. Reg. 4974 (implementing programmatic changes). For example, HHS has introduced an initiative to allow certain suppliers to obtain prior authorization before delivering certain services, and a demonstration to furnish provider education and to allow correction of certain claims at lower levels of administrative review. JA96-JA98. HHS has also implemented a review process to promote accuracy of decisions by Medicare contractors. JA101-JA102.

As noted, the Secretary has also implemented significant changes to the RAC program to decrease the extent to which it generates new appeals. *See* JA96; JA140-JA141*; see also* JA144-JA146 (describing further changes to the RAC program made in October 2016). For example, the agency imposed new limits on the type of RAC review that generated a majority of the RAC appeals at OMHA, substantially reducing the number of such appeals. JA141. These measures have contributed to the

significant decrease in the number of RAC-related appeals reaching OMHA. JA140-JA141; JA157.

As a result of the agency's various efforts, the backlog, which stood at over 800,000 appeals in July 2014, *AHA*, 812 F.3d at 187, and which the Court described as "only worsening," *id.* at 193, had decreased to fewer than 658,000 appeals as of December 2016 (JA168). In total, HHS's administrative actions are expected to result in nearly 50% fewer appeals in the backlog than would have been present had HHS not taken those actions. JA100; *see* JA156 (showing projections that hundreds of thousands of appeals will be saved as a result of administrative measures). This progress in no sense diminishes the urgency of obtaining additional resources and new authorities from Congress to eliminate the administrative backlog. But there is no doubt that the agency is using all available resources to achieve that result.

4. This Court has made clear that "[e]quitable relief, particularly mandamus, does not necessarily follow a finding of a violation." *In re Barr Labs., Inc.*, 930 F.2d 72, 74 (D.C. Cir. 1991); *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 551 (D.C. Cir. 1999) (similar); *see also Weber v. United States*, 209 F.3d 756, 760 (D.C. Cir. 2000) ("Mandamus is an extraordinary remedy whose issuance is guided by equitable principles.").

When Congress does "not provide enough funding," courts must allow for "the substantive authority of the Secretary to take appropriate action to cope with the administrative impossibility of applying the commands of the substantive statute."

Alabama Power Co. v. Costle, 636 F.2d 323, 359 (D.C. Cir. 1979); *see also Morton v. Ruiz*, 415 U.S. 199, 231 (1974) (where Congress inadequately funds a benefit program, it is "incumbent" on the agency to develop criteria that exclude some individuals from benefits to which they are otherwise statutorily entitled). As this Court has stressed, when delay "stem[s] from a lack of resources," it is "'a problem for the political branches to work out.'" *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1101 (D.C. Cir. 2003) (quoting *Barr Labs.*, 930 F.2d at 75); *see Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 56 (4th Cir. 2016) (concluding that if the backlog at issue here is "attributable to Congress' failure to fund the program more fully or otherwise to provide a legislative solution, it . . . [is] a problem for Congress, not the courts, to address").

The appropriations power belongs to Congress, *see OPM v. Richmond,* 496 U.S. 414, 424 (1990), and if Congress does not appropriate the funding necessary "for a statutorily mandated program, the Executive obviously cannot move forward." *In re Aiken Cty.*, 725 F.3d 255, 259 (D.C. Cir. 2013). Here, HHS has no ability to comply with an order requiring it to adjudicate the backlogged appeals because Congress has not provided the agency sufficient resources to do so.

Likewise, congressionally-imposed restrictions on appropriations preclude HHS from resolving the backlog through means other than adjudication, such as mass settlements. Congress has imposed strict limitations on the payment of Medicare funds, *see supra* p. 20, and mandamus cannot properly require the agency to make

payments that contravene those statutory limitations. *See OPM*, 496 U.S. at 420 (recognizing "the duty of all courts to observe the conditions defined by Congress for charging the public treasury"); *see also I.N.S. v. Pangilinan*, 486 U.S. 875, 883 (1988) ("[C]ourts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law").

The backlog stems from inadequate appropriations and the agency has no lawful means of eliminating the backlog absent additional appropriations. A writ of mandamus cannot properly issue where an agency has marshaled all its available resources to meet statutory requirements, and the district court erred in holding otherwise.

B. Even If Plaintiffs Had Demonstrated Entitlement To A Writ, The District Court Could Not Properly Order Relief That Compels The Agency To Make Payments Unauthorized By Statute

Even if some form of mandamus relief were appropriate, the district court's order still must be set aside.

1. The district court did not question that it could not require the agency to spend funds that Congress has not appropriated. Its order nevertheless frustrates the appropriations power by effectively compelling the government to engage in blanket settlements without adequate regard to the merit of the claims at issue.

While the district court's order purports only to require HHS to resolve the backlog without specifying a particular means (JA165), in practice, the order can only

be understood as requiring blanket settlements that do not account for the underlying merits of the claims involved. There is no dispute that HHS cannot resolve the backlog through adjudication. Plaintiffs' only proposal for eliminating the backlog is that the Secretary should be required to offer "settlements to certain broad groups of Medicare providers and suppliers." JA163; *see also* Pls.' Mot. Summ. J. 5 (Oct. 14, 2016) (Dkt. No. 39) (suggesting that the Court order the Secretary to offer "*all* hospitals" or "*all* Medicare Part A providers" the opportunity to settle all of their claims under generally available terms unrelated to the merits of the specific claims being settled); Pls.' Summ. J. Reply 5 (Nov. 15, 2016) (Dkt. No. 43) (insisting that "settlements must be offered on a large enough scale to materially decrease the backlog in the short term" and cannot involve "resource-intensive negotiation" tied to the merits of individual claims).[12] The district court itself previously described the view that the backlog might be resolved by simply ordering HHS to meet the statutorily deadlines as "extremely wishful thinking." JA130.

As HHS explained to the district court, settlements on the scale needed to comply with the district court's order cannot reflect the underlying merits of the

[12] Plaintiffs also asked that the Secretary be required to institute certain other programmatic changes for purposes such as "alleviat[ing] the financial strain on providers" (JA163), but it is undisputed that adopting these changes would not enable the Secretary to comply with the district court's mandamus order to reduce and ultimately eliminate the backlog. Indeed, they would exacerbate the backlog. JA148-JA149. Plaintiffs' only proposal for eliminating the backlog was global settlements.

claims. The remaining backlogged claims are largely not homogeneous, making it impossible for HHS to set merits-based settlement terms applicable on a scale remotely sufficient to meet the targets set by the district court's order. JA142. For this reason, an order requiring the elimination of the backlog effectively requires the agency to "make payment on Medicare claims regardless of the merit of those claims." JA165.

The agency may not lawfully disregard statutory payment criteria set by Congress. *See supra* p. 20. The agency may settle claims on terms that bear a reasonable relation to those claims and reflect litigation risk. *See* 42 C.F.R. § 401.613(a), (c)(2); *id.* § 405.376(h). Indeed, as the government explained in district court, the agency is actively pursuing merits-based settlements of backlogged claims. *See* JA151-JA152 (noting the agency "is committed to offering individualized settlements to providers based on individualized information and assessments"); JA141-JA142 (describing one targeted settlement of 380,000 appeals); JA143 (settlement conference facilitation); JA98-JA99 (settlement conference facilitation and program to resolve appeals through statistical sampling). But there is no authority for the agency to expend Medicare funds on settlements that are not tied to the merits of the underlying claims, as would be necessary to complete the bulk settlements needed to comply with the court's order. The agency explained that if "providers and suppliers receive a blanket global settlement not based on their individual error rates and not taking into account any concerns . . . about fraudulent or abusive billing, the

Medicare Trust Funds could be forced to pay out substantially more than they would had the claims been adjudicated in the normal course." *See* JA151.

The resulting incursion on the fisc would be dramatic. The total billed amounts-in-controversy are approximately $6.6 billion. JA170.[13] And all evidence to date indicates that the majority of these claims would be rejected in ALJ hearings. Claims in the backlog have already been rejected three times; first in an initial determination or a RAC audit, and then at two prior levels of administrative appeal. *See supra* p. 5. In 2016, ALJs reversed (*i.e.*, ruled for the challenger) in just 28% of cases. JA170. Even this figure likely overstates the percentage of meritorious claims in the backlog because, over the past year, the agency has undertaken administrative initiatives (including targeted settlements tied to the merits of underlying claims) that have removed meritorious claims from the backlog. *Id.* As a result, the remaining claims are, on average, even weaker.

Nor can the backlog be eliminated by offering global settlements for payments that approximate the overall success rate of providers. If the Secretary offered, for example, to pay claims at thirty cents on the dollar, there would be a massive risk of adverse selection: only providers with the weakest claims would agree to settle. JA151. Moreover, any effort to reach a fair settlement would be particularly futile

[13] Actual amounts paid may be lower because providers and suppliers generally bill Medicare at higher amounts than Medicare fee schedules allow, but the amount of money at issue is still significant. JA170.

against the backdrop of a mandamus order, which gives providers enormous leverage to demand payments far greater than the amounts to which they are entitled. And addressing the backlog through settlements might well be self-defeating in any case; if the Secretary were to begin offering settlements without regard to merit, those offers might well "encourage [providers] to flood the appeals system with every denied claim—regardless of merit—with that the hope that it would eventually also be paid," thereby paradoxically compounding the backlog. JA169; *see also* JA151. Thus, broad-based settlements cannot cure the backlog.

2. The district court declared that it "need not dive into the parties' debate over" whether the Secretary is authorized to settle claims without regard to their substantive merit. JA165. The court was wrong. The parties agreed that settlements of this kind were the only conceivable means for meeting the court's schedule. It was thus incumbent on the district court to determine whether it could properly order the Secretary to pay claims without regard to their merit. Had it confronted the question, the court presumably would have recognized that no such order can rightly issue. *See OPM*, 496 U.S. at 420.

The district court underscored its error when it reasoned that "the statutory prohibition on improper payments is not the *only* legal constraint on HHS's claims-adjudication process" and the agency is "*also* bound by statutorily mandated deadlines." JA165 (emphases added). A court has no authority to enforce a statutory timetable by requiring HHS to violate legal constraints on its claims-adjudication

process. *See supra* pp. 22-24. And even if a court possessed such authority, there is no reason to conclude that it would be appropriate to compel hundreds of millions of dollars in unauthorized payments to resolve the administrative backlog and vindicate the ALJ-adjudication timetable.

On the contrary, Congress anticipated that when the ninety-day timeline was unmet, the "consequence[]" would be that providers would "escalate" their claims within the agency, skipping over the ALJ stage and proceeding directly to the fourth and final stage of administrative review. 42 U.S.C. § 1395ff(d)(3)(A); *see AHA*, 812 F.3d at 191 ("Congress anticipated that violations might occur with some measure of regularity" and included the escalation provision as a result.). This provision is consistent with the statutory command that the Secretary may not pay claims for items or services that are not covered by Medicare "[n]otwithstanding any other provision" of the Medicare statute. 42 U.S.C. § 1395y(a). Mandated blanket settlements of claims not properly payable as the remedy for a violation of the adjudication timetable is also directly at odds with the many statutorily-mandated program-integrity measures to identify wasteful and fraudulent claims. *See generally id.* § 1395ddd. And if Congress viewed the ninety-day timetable as a paramount concern that could supersede other requirements of the Medicare statute, it surely would not

have used a line-item appropriation to fund an insufficient number of ALJs to meet that deadline.[14]

3. If this Court were to conclude that plaintiffs had identified a basis on which a writ could properly issue, it should make clear that any relief ordered by the district court cannot force the agency to abandon its statutory responsibilities and make payments unauthorized by statute.

In district court, HHS offered several examples of remedies that would prevent the agency from elevating "discretionary" decisions above the obligation to provide timely ALJ hearings, *AHA*, 812 F.3d at 193, while still not compelling any violation of the law. The court could, for example, have required the agency to continue to submit status reports and to attest to its ongoing attention to the backlog. The court could also have required HHS to maintain the many initiatives it has undertaken to combat the backlog. *See generally* JA95-JA105. The agency could be required to continue to maintain limits on the look-back review periods for RAC review that have been temporarily instituted. JA146. And to address concerns about the financial hardship that the backlog has created for some providers, the court could have

[14] To the extent that the Court concludes that there is a statutory conflict between the ninety-day deadline and other provisions of the Medicare statute, the agency is owed deference in determining how to resolve that tension. *See, e.g.*, *Scialabba v. Cuellar de Osorio*, 134 S. Ct. 2191, 2207 (2014) (plurality opinion) ("When an agency . . . resolves statutory tension, ordinary principles of administrative deference require us to defer.") (citing *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007)).

ordered OMHA to prioritize pending appeals where the provider meets existing definitions of financial hardship. *See* JA153.

It would not be appropriate to order any of these measures for the reasons discussed in Part A.4, *supra*. But, unlike the relief actually ordered by the district court, none would require the agency to contravene its statutory responsibilities and provide reimbursements for claims that are not properly payable under the Medicare statute.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and judgment should be entered in favor of the Secretary.

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FEBRUARY 2017

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a). This brief contains 7,520 words.

s/ Joshua Salzman
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CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Joshua Salzman
Joshua M. Salzman

ADDENDUM

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42 U.S.C. § 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner, a clinical nurse specialist, or a physician assistant (as those terms are defined in section 1395x(aa)(5) of this title) who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,[] or, in the case of services described in subparagraph (C), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that—

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for

treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; such services are or were furnished while the individual was under the care of a physician, and, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1395m(m) of this title, and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during

periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services, there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1395cc(d) of this title (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1395x(k)(4) of this title, including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the day on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual—

(A) (i) in the first 90-day period and

(I) the individual's attending physician (as defined in section 1395x(dd)(3)(B) of this title)(which for purposes of this subparagraph does not include a nurse practitioner), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care,

each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness,

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program;

(C) such care is being or was provided pursuant to such plan of care;

(D) on and after January 1, 2011 (and, in the case of clause (ii), before October 6, 2014)—

(i) a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary); and

(ii) in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of such cases for all programs under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary);

(E) on and after October 6, 2014, in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of all cases of individuals provided hospice care by the program under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as

determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day- care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

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42 U.S.C. § 1395g. Payments to providers of services

(a) Determination of amount

The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the Government Accountability Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period.

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42 U.S.C. § 1395*l*. Payment of benefits

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(e) Information for determination of amounts due. No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

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42 U.S.C. § 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e) of this section, payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service; and

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1395x(s)(2) of this title, such services are or were medically required;

(C) in the case of physical therapy services or outpatient occupational therapy services, (i) such services are or were required because the individual needed physical therapy services or occupational therapy services, respectively, (ii) a plan for furnishing such services has been established by a physician or by the qualified physical therapist or qualified occupational therapist, respectively, providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(D) in the case of outpatient speech pathology services, (i) such services are or were required because the individual needed speech pathology services, (ii) a plan for furnishing such services has been established by a physician or by the speech pathologist providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(E) in the case of comprehensive outpatient rehabilitation facility services, (i) such services are or were required because the individual needed skilled rehabilitation services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician; and(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

For purposes of this section, the term "provider of services" shall include a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) of this title (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1395x of this title), or if, in the case of a public health agency, such agency meets the requirements of section 1395x(p)(4)(B) of this title (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1395x of this title), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of subsection (g) or (ll)(2) of section 1395x of this title) with respect to the furnishing of outpatient occupational therapy services or outpatient speech-language pathology services, respectively.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day- care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

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42 U.S.C. § 1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services—

(1) (A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,

(E) in the case of research conducted pursuant to section 1320b-12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title, and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(oo) of this title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1395m(d) of this title,

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1395w-3a(c)(6)(C) of this title for which payment is made under part B of this subchapter that is furnished in a competitive area under section 1395w-3b of this title, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B of this subchapter,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1395x(ggg) of this title), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1395x(hhh)(1)) of this title, which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, in the case of services for which payment may be made under section 1395qq(e) of this title, and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, physicians' services and ambulance

services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1395x(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1395x(s)(10) of this title and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1);

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1395x(s)(12) of this title;

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A of this subchapter in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1395x(s)(2)(K) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the hospital or critical access hospital;

(15) (A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of subchapter XI of this chapter) or a carrier under section 1395u of this title has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1395w-4(i)(2)(B) of this title applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997 [42 U.S.C.A. 14401 et seq.];

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1395w-3(a) of this title) by an entity other than an entity with which the Secretary has entered into a contract under section 1395w-3(b) of this title for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1395yy(e)(2)(A)(i) of this title and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1395x(s)(2)(D) of this title, which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1395a(b) of this title;

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing

requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1395x of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h) of this section, for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1395m(e)(1)(B) of this title for which payment is made under the fee schedule established under section 1395w-4(b) of this title and that are furnished by a supplier (as defined in section 1395x(d) of this title), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1395m(e)(2)(B) of this title;

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1395x(aa)(3)(B) of this title.

In making a national coverage determination (as defined in paragraph (1)(B) of section 1395ff(f) of this title) the Secretary shall ensure consistent with subsection (l) of this section that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

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42 U.S.C. § 1395ff. Determination; appeals

(a) Initial determinations

(1) Promulgations of regulations

The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a quality improvement organization under section 1320c-3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w-22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI of this chapter.

(2) Deadlines for making initial determinations

(A) In general

Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits from an individual as described in paragraph (1). Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 45-day period.

(B) Clean claims

Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general

In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations

(i) Appeal rights

No initial determination may be reconsidered or appealed under subsection (b) of this section unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker

No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines

(i) Filing for redetermination

A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations

Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction

For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations

With respect to an initial determination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the determination shall include—

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations

With respect to a redetermination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the redetermination shall include—

(i) the specific reasons for the redetermination;

(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and

(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights

(1) In general

(A) Reconsideration of initial determination

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2), to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the "Commissioner of Social Security" or the "Social Security

Administration" in subsection (g) or (l) of section 405 of this title shall be considered a reference to the "Secretary" or the "Department of Health and Human Services", respectively.

(B) Representation by provider or supplier

(i) In general

Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary

Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation

If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary

The provisions of section 405(j) of this title and of section 406 of this title (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment

The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals

(i) Reconsiderations

Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date

the individual receives notice of the redetermination under subsection (a)(3) of this section, or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary

The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 405 and 406 of this title.

(E) Amounts in controversy

(i) In general

A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.

(ii) Aggregation of claims

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve—

(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or

(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts

For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(F) Expedited proceedings

(i) Expedited determination

In the case of an individual who has received notice from a provider of services that such provider plans—

(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or

(II) to discharge the individual from the provider of services, the individual may request, in writing or orally, an expedited determination or an

expedited reconsideration of an initial determination made under subsection (a)(1) of this section, as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review

For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations

The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review

(A) In general

The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations

If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review

(i) In general

If the appropriate review entity—

(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

(II) fails to make such determination within the period provided under subparagraph (B),

then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing

Such action shall be filed, in the case described in—

(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue

Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy

Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this subchapter.

(D) Review entity defined

For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers

A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c) of this section, unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors

(1) In general

The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1) of this section. Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor

For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1) of this section, and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements

Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general

The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations

(i) In general

The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience

(including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations

(I) National coverage determinations

If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1395y(a) of this title, such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations

If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination

In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions

(i) Reconsiderations

Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline

In the case of a failure by the qualified independent contractor to mail the notice of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party's right to such hearing.

(iii) Expedited reconsiderations

The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) of this section as follows:

(I) Deadline for decision

Notwithstanding section 416(j) of this title and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary

In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges

A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1320c-3(e) of this title as in effect on the date that precedes December 21, 2000.

(iv) Extension

An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers

The requirements of subsection (g) of this section shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision

Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate), and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal

under this section and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title) an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements

Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A of this subchapter or part B of this subchapter of such decision.

(G) Dissemination of decisions on reconsiderations

Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1395h of this title), carriers (under section 1395u of this title), quality improvement organizations (under part B of subchapter XI of this chapter), Medicare+Choice organizations offering Medicare+Choice plans under part C of this subchapter, other entities under contract with the Secretary to make initial determinations under part A of this subchapter or part B of this subchapter or subchapter XI of this chapter, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(H) Ensuring consistency in decisions

Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection

(i) In general

Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected

Each qualified independent contractor shall keep accurate records of each decision made, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(I) Specific claims that give rise to appeals.

(II) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(III) Situations suggesting the need for changes in national or local coverage determination.

(IV) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting

Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary

The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements

(i) In general

Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

(I) is not a related party (as defined in subsection (g)(5) of this section);

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation

Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation

Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors

The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability

No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice

(1) Hearing by administrative law judge

(A) In general

Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) of this section and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) Waiver of deadline by party seeking hearing

The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review

(A) In general

The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure

In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines

(A) Hearing by administrative law judge

In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party's right to such a review.

(B) Departmental Appeals Board review

In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review.

(4) Notice

Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include—

(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the decision; and

(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

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42 U.S.C. § 1395ddd. Medicare Integrity Program

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(h) Use of recovery audit contractors

(1) In general

Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this subchapter with respect to all services for which payment is made under this subchapter. Under the contracts—

(A) payment shall be made to such a contractor only from amounts recovered;

(B) from such amounts recovered, payment;

(i) shall be made on a contingent basis for collecting overpayments; and

(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

(C) the Secretary shall retain a portion of the amounts recovered which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of activities conducted under the recovery audit program under this subsection.

(2) Disposition of remaining recoveries

The amounts recovered under such contracts that are not paid to the contractor under paragraph (1) or retained by the Secretary under paragraph (1)(C) or paragraph (10) shall be applied to reduce expenditures under this subchapter.

(3) Nationwide coverage

The Secretary shall enter into contracts under paragraph (1) in a manner so as to provide for activities in all States under such a contract by not later than January 1, 2010 (not later than December 31, 2010, in the case of contracts relating to payments made under part C or D of this subchapter).

(4) Audit and recovery periods

Each such contract shall provide that audit and recovery activities may be conducted during a fiscal year with respect to payments made under this subchapter—

(A) during such fiscal year; and

(B) retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year).

(5) Waiver

The Secretary shall waive such provisions of this subchapter as may be necessary to provide for payment of recovery audit contractors under this subsection in accordance with paragraph (1).

(6) Qualifications of contractors

(A) In general

The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor unless the contractor has staff that has the appropriate clinical knowledge of, and experience with, the payment rules and regulations under this subchapter or the contractor has, or will contract with, another entity that has such knowledgeable and experienced staff.

(B) Ineligibility of certain contractors

The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor to the extent the contractor is a fiscal intermediary under section 1395h of this title, a carrier under section 1395u of this title, or a medicare administrative contractor under section 1395kk-1 of this title.

(C) Preference for entities with demonstrated proficiency

In awarding contracts to recovery audit contractors under paragraph (1), the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, under the Medicaid program under subchapter XIX of this chapter, or under this subchapter.

(7) Construction relating to conduct of investigation of fraud

A recovery of an overpayment to a individual or entity by a recovery audit contractor under this subsection shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(8) Annual report

The Secretary shall annually submit to Congress a report on the use of recovery audit contractors under this subsection. Each such report shall include information on the performance of such contractors in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of such contractors and savings to the program under this subchapter.

(9) Special rules relating to parts C and D

The Secretary shall enter into contracts under paragraph (1) to require recovery audit contractors to—

(A) ensure that each MA plan under part C of this subchapter has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

(B) ensure that each prescription drug plan under part D of this subchapter has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

(C) examine claims for reinsurance payments under section 1395w-115(b) of this title to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under paragraph (2) of that section; and

(D) review estimates submitted by prescription drug plans by private plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.

(10) Use of certain recovered funds

(A) In general

After application of paragraph (1)(C), the Secretary shall retain a portion of the amounts recovered by recovery audit contractors for each year under this section which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of, subject to subparagraph (B), carrying out sections 1395l(z) of this title, 1395m(l)(16) of this title, and 1395kk-1(a)(4)(G) of this title, carrying out section 514(b) of the Medicare Access and CHIP Reauthorization Act of 2015, and implementing strategies (such as claims processing edits) to help reduce the error rate of payments under this subchapter. The amounts retained under the preceding sentence shall not exceed an amount equal to 15 percent of the amounts recovered under this subsection, and shall remain available until expended.

(B) Limitation

Except for uses that support claims processing (including edits) or system functionality for detecting fraud, amounts retained under subparagraph (A) may not be used for technological-related infrastructure, capital investments, or information systems.

(C) No reduction in payments to recovery audit contractors

Nothing in subparagraph (A) shall reduce amounts available for payments to recovery audit contractors under this subsection.

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