American Hospital Association

Legislative Advisory

December 7, 2016

THE 21ST CENTURY CURES ACT

AT A GLANCE

Summary:

On Dec. 7, the Senate passed the 21st Century Cures Act, and President Obama is expected to sign the bill, which passed the House Dec. 1, into law. This bill is primarily designed to advance the development of medical treatments and cures through investments in research and updates to how new therapies are developed and approved. The major components of the bill fund new initiatives at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). Specifically, the bill authorizes $4.8 billion for the NIH to fund new initiatives around precision medicine, cancer, neuroscience, and regenerative medicine. The bill also provides $500 million over 10 years to the FDA to facilitate the development of new drugs and devices, as well as modernizing clinical trials and the development of evidence.

In addition, the law contains several important hospital-related provisions, including:

- exceptions from the outpatient prospective payment system (OPPS) site-neutral payments for certain off-campus hospital outpatient departments that were under construction at the time the site-neutral statutory provisions were passed in November 2015;
- changes to health information technology (IT) policy, such as introducing penalties for "information blocking," taking steps to advance interoperability, adding new certification and transparency requirements for developers of health IT, and taking steps to improve patient access to health records;
- adjustments to the Hospital Readmissions Reduction Program (HRRP) to account for socioeconomic status;
- providing for an additional 12 months of relief from the long-term care hospital (LTCH) 25% Rule;
- prohibitions on enforcement of the "direct supervision" regulations for 2016 for outpatient therapeutic services provided in critical access hospitals and certain small, rural hospitals;
- reforms to the mental health system, including provisions related to mental health parity, integration with physical health services, workforce development, and privacy provisions, among others;
- providing $1 billion in grants to states to help address the opioid epidemic; and
- extending the Rural Community Hospital Demonstration Program for five years.

In total, the act authorizes approximately $6.3 billion in new spending, which will be paid for from a $3.5 billion reduction in the Prevention and Public Health Fund, along with other savings and anticipated revenue.

Our Take:

This bill helps improve hospitals' ability to treat some of the most vulnerable patients through its inclusion of important provisions related to hospital outpatient services, the HRRP, LTCHs, rural health care, and behavioral health and opioids. However, the AHA will continue to work with Congress to address some outstanding issues, including the relocation of hospital outpatient departments so they can continue to provide patient access to care and making needed changes to allow for flexibility in use of electronic health records.

Further Questions:

If you have questions, please contact AHA Member Relations at 1-800-424-4301.

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BACKGROUND

On Dec. 7, the Senate passed the 21st Century Cures Act, and President Obama is expected to sign the bill, which passed the House Dec. 1, into law. Among its key provisions, the law advances the development of medical treatments and cures through investments in research and updates to how new therapies are developed and approved. The law also includes a number of important hospital-related provisions, including exceptions from outpatient prospective payment system (OPPS) site-neutral payments for certain off-campus hospital outpatient departments that were under construction at the time the site-neutral statutory provisions were passed in November 2015, among others. In total, the Act authorizes approximately $6.3 billion in new spending, which will be paid for with $3.5 billion from the Prevention and Public Health Fund, along with other savings and anticipated revenue. This advisory contains a summary of the law's key provisions, including Congressional Budget Office (CBO) scores, where available.

TITLE I: INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

This title establishes the major components of the legislation, including by authorizing more than $4.8 billion to the National Institutes of Health (NIH) and $500 million to the Food and Drug Administration (FDA) over 10 years for new initiatives. It would also provide more than $1 billion over two years for grants to states to supplement opioid abuse prevention and treatment activities. Specific provisions of interest include the following.

NIH Innovation Projects (Sec. 1001)
This provision was not scored by CBO[1]

This section establishes the "NIH Innovation Account" to fund the Precision Medicine Initiative ($1.4 billion); the Brain Research through Advancing Innovative Neurotechnologies Initiative (''BRAIN Initiative'') ($1.5 billion); cancer research ($1.8 billion); and grants and contracts for clinical research to further the field of regenerative medicine using adult stem cells ($30 million).

FDA Innovation Projects (Sec. 1002)
This provision was not scored by CBO

This section establishes an FDA Innovation Account and authorizes appropriations in the amount of $500 million over 10 years to implement provisions in Title III (described below) related to the development of new drugs, drug therapies, antimicrobials, medical devices and medical countermeasures as well as modernizing clinical trials, evidence development and improving patient access to therapies and information.

[1] All CBO information is from the Nov. 28, 2016 CBO score sheet titled: Direct Spending And Revenue Effects For H.R. 34, The 21st Century Cures Act.

Account for the State Response to the Opioid Abuse Crisis (Sec. 1003)
This provision was not scored by CBO

This section provides $1 billion ($500,000 each for FY 2017 and FY 2018) in grants to states to help address the opioid epidemic and allows the Secretary of Health and Human Services to give preference to states where opioid use disorders are more prevalent. Among other activities, states could use the funding to improve prescription drug monitoring programs, train health care practitioners in best practices for prescribing opioids and pain management, and support access to health care services.

TITLE II: DISCOVERY

This title includes a number of provisions related to the NIH operations. It reauthorizes the NIH through 2020 and directs the NIH to establish a strategic plan. Provisions in this title focus on advancing research in certain priority areas, such as neurological diseases and pediatric conditions; improving the NIH's data collection efforts; encouraging collaboration across researchers; and reducing administrative burden on researchers, among other things.

Subtitle A: NIH Reauthorization (Secs. 2001-2002)
This subtitle was not scored by CBO

This subtitle reauthorizes the NIH from 2017 to 2020 with an annual appropriation of between $34 and $36 billion. It also directs the NIH to establish research competitions to identify treatments or cures for certain conditions, including 1) those for which current investment in research is disproportionately small relative to federal expenditures on prevention and treatment; 2) serious conditions that represent a significant disease burden; and 3) conditions for which a treatment or cure may provide significant return on the research investment.

Subtitle B: Advancing Precision Medicine (Secs. 2011-2014)
This subtitle was not scored by CBO

This subtitle "encourages" the Secretary of HHS to establish a "Precision Medicine Initiative" to advance the use of genomic technologies in the prevention, diagnosis, and treatment of disease. It outlines potential components of such an initiative, including the establishment of a network of scientists and a particular focus on including diverse cohorts of individuals in research, among other items. This subtitle also addresses the privacy protections for individuals who participate in public and privately funded research, and specifically exempts from disclosure biomedical information from a research participant that may be used to identify the individual. HHS will be required to issue "certificates of confidentiality" to researchers that would require that they abide by enhanced privacy protections for research participants. This subtitle also allows the Secretary to require that recipients of NIH awards share scientific data, with explicit exemptions related to

the privacy of research participants and proprietary or commercially sensitive data.

Subtitle C: Supporting Young Emerging Scientists (Secs. 2021-2022)
This subtitle was not scored by CBO

This subtitle establishes the "Next Generation of Researchers Initiative" to coordinate and promote policies and programs to increase opportunities for new researchers. It also modifies the current loan repayment program for researchers by increasing the amount payable by the NIH from $35,000 to $50,000 annually and modifying the specific intramural and extramural research areas to target for loan repayment. With respect to intramural research, the NIH is directed to focus on: general research; AIDS; and research from professionals from disadvantaged backgrounds. With respect to extramural research, the NIH is required to focus on: contraception or infertility; pediatrics, including pediatric pharmacological; minority health disparities; clinical research; and clinical research conducted by professionals from disadvantaged backgrounds. The Director of the NIH is permitted to modify the areas of focus based on emerging scientific or workforce needs. The subtitle also requires that the Government Accountability Office (GAO) submit a report to Congress on the NIH's efforts to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such women, racial and ethnic minorities, and other groups.

Subtitle D: NIH Planning and Administration (Secs. 2031-2044)
This subtitle was not scored by CBO

This subtitle includes a number of provisions related to NIH operations and reporting, with overarching themes of public-private collaboration, internal coordination, accountability, and reduction of administrative burden on researchers. It requires that the NIH develop a strategic plan at least every six years, beginning no later than two years after passage of the Act. The plan, among other things, identifies strategic research priorities and objectives based on an assessment of the state of medical and behavioral health research and emerging scientific opportunities and needs. It updates several NIH reporting requirements, and makes changes to the terms for the directors of national research institutes and national centers. Many of the provisions specifically direct the NIH to focus on diverse and often under-represented population cohorts, including women, children and racial/ethnic, sexual and gender minority populations. For example, under this title, the NIH will establish a Task Force on Research Specific to Pregnant Women and Lactating Women. Other specific sections of interest include:

- ***Reducing Administrative Burden for Researchers*** (Sec. 2034)
  This provision was not scored by CBO

  This section directs the Secretary to review regulations and policies to reduce administrative burden on researchers with a specific focus on policies related to disclosure of financial conflicts, monitoring of

subrecipients, reporting of financial expenditures, and care and use of laboratory animals. It also establishes a "Research Policy Board" to provide information on the effects of regulations related to federal research requirements and make recommendations on how to modify and harmonize regulations and policies to minimize administrative burden.

- ***High-risk, High-reward Research*** (Sec. 2036)
  This provision was not scored by CBO

  This section encourages the NIH to conduct and support “high-risk, high-reward” research, and authorizes the NIH to use transactions other than contracts, grants or cooperative agreements for the Precision Medicine Initiative and for up to half of the funds available in the Common Fund.

- ***National Center for Advancing Translational Sciences (NCATS)*** (Sec. 2037)
  This provision was not scored by CBO

  This section revises the NCATS to increase its support of Phase II and III clinical trial activities for treatments of certain rare diseases or conditions.

- ***Collaboration and Coordination to Enhance Research*** (Sec. 2038)
  This provision was not scored by CBO

  This section includes a number of discrete provisions that direct the NIH to improve data accuracy; enhance collaboration across NIH-funded projects; and focus research on women, children, and minority populations. This section also directs the NIH to review certain basic research policies for potential revision, including relevant biological variables including sex, and how differences between male and female cells, tissues, or animals may be examined and analyzed.

- ***Enhancing the Rigor and Reproducibility of Scientific Research*** (Sec. 2039)
  This provision was not scored by CBO

  This section requires the Secretary to convene a working group to develop recommendations for a formal policy to enhance the rigor and reproducibility of NIH-funded research. The working group is required to consider pre-clinical experiment design, including analysis of sex as a biological variable; clinical experiment design; applicable levels of rigor in statistical methods, methodology, and analysis; and data and information sharing.

Subtitle E: Advancement of the NIH Research and Data Access
(Secs. 2051-2054)
This subtitle was not scored by CBO

This subtitle deals primarily with the clinical trials database. Specifically, this subtitle makes technical updates to the database to allow device manufacturers to voluntarily submit data from clinical trials that have not yet been cleared or approved. It also clarifies how a combination drug/device is classified in the database. This subtitle also directs the NIH to review and update policies to improve the quality of data in the database and require monitoring of activities to encourage compliance with database policies. Finally, this subtitle requires the Secretary to consult with public and private stakeholders on recommendations related to the clinical trial registry.

Subtitle F: Facilitating Collaborative Research (Secs. 2061-2063)
This subtitle was not scored by CBO

This subtitle specifically supports research efforts related to neurological diseases and conditions and tick-borne diseases. Specifically, it directs the Secretary to establish the "National Neurological Conditions Surveillance System" to collect data on patient demographics, disease risk factors, and diagnosis and progression markers, among other data. It also establishes a federal "Tick-Borne Disease Working Group" to review HHS activity in this area and make recommendations for future work. It also directs the Secretary to issue guidance related to remote access of protected health information, including by establishing a working group to study and report on whether the uses and disclosures of protected health information for research purposes should be modified.

Subtitle G: Promoting Pediatric Research (Secs. 2071-2072)
This subtitle was not scored by CBO

This subtitle directs the NIH to continue to support the National Pediatric Research Network, and encourages the NIH and FDA to work with the European Union, industry, and others to establish a global pediatric clinical study network.

TITLE III: DEVELOPMENT

This title includes a wide-ranging series of provisions intended to streamline regulatory processes and equip federal health agencies with the tools they need to help accelerate the innovated development of drug therapies.

Subtitle A: Patient-focused Drug Development (Secs. 3001-3004)
This subtitle was not scored by CBO

This subtitle requires the FDA to take patient experience data into consideration in the development and approval of new drugs. The FDA would be required to issue

statements and develop guidance and reports on how it will collect and use patient experience data.

Subtitle B: Advancing New Drug Therapies (Secs. 3011-3016)
This subtitle was not scored by CBO

This subtitle establishes a review pathway at FDA for biomarkers and other drug development tools that can be used to help shorten drug development time and reduce the failure rate in drug development. It also clarifies the FDA's authority with regard to genetically targeted drugs for rare diseases, including allowing drug sponsors to use data from previously approved drug applications if there is a similar technology. Further it reauthorizes (with modifications) a program that encourages treatments for rare pediatric diseases, requires the GAO to review and report on the impact of all of the existing priority review voucher programs, updates the orphan drug grant program to allow for observation studies and allows grants for studying continuous drug manufacturing.

Subtitle C: Modern Trial Design and Evidence Development
(Secs. 3021-3024)
This subtitle was not scored by CBO

This subtitle requires FDA to hold meetings and issue guidance about the use of adaptive designs and novel statistical modeling for sponsors developing new drug applications. It also requires FDA to develop and implement a program to evaluate the potential use of real world evidence (i.e. data about a drug from sources other than randomized clinical trials) to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements. Further, the Secretary of HHS would be required to harmonize differences between the HHS and FDA regulations protecting human research subjects and streamline the institutional review board process for multi-site clinical trials. Finally, it would provide FDA the flexibility to waive or alter informed consent requirements for clinical trials with minimal risk.

Subtitle D: Patient Access to Therapies and Information
(Secs. 3031-3038)
This subtitle was not scored by CBO

This subtitle allows FDA to rely on qualified data summaries to support the approval of an application for a new indication of an already approved drug. It also requires drug manufacturers to have publicly accessible compassionate use policies for investigational drugs that treat serious diseases. In addition, this subtitle provides for expedited approval pathway for regenerative advanced therapeutic products – therapies which aim to fully heal damaged tissues and organs. The efforts to expand regenerative medicine therapies includes the development of FDA guidance, a progress report to Congress, and the development of standards and regulations for regenerative medicine. Moreover, the subtitle also expands the scope of permitted manufacturer communications regarding health care economic information regarding the economic

consequences of use of a drug. Finally, it improves the regulation of combination products, which are products that contain both a drug and device.

Subtitle E: Antimicrobial Innovation and Stewardship (Secs. 3041-3044)
This subtitle was not scored by CBO

This subtitle includes provisions to prioritize and expedite the FDA review and approval process for antimicrobial drugs and devices, to promote data collection, analysis, and information sharing designed to improve stewardship of existing antimicrobials and enable better prevention or cure of infections. Specific provisions of interest include:

- Requiring the CDC to use the National Healthcare Safety Network (NHSN) to monitor both the use of antimicrobial drugs and any changes in bacterial and fungal resistance to drugs. These data will be made publicly available and used to assess and report on national and regional trends in antimicrobial stewardship and drug resistance. Hospitals and other healthcare providers will be encouraged to submit data. It also requires the CDC and the FDA to distribute educational materials related to antimicrobial stewardship programs or practices to health care facilities;
- Requiring the CDC to continue to support state and local efforts to combat drug resistant organisms, including tracking local or state prevalence of drug resistant organisms, assisting with efforts to prevent the spread of drug resistant organisms, and improving antimicrobial stewardship programs;
- Allowing the FDA to approve a new antimicrobial drug for use in a limited population if some patients have a life-threatening or serious infection for which no other treatment is available. This would allow, under special circumstances, the expedited use of a new drug for some patients. This section provides the FDA with the authority to ensure that the labeling of drugs approved in this manner reflects the limited purposes and populations for which the drug has been approved and to review the promotional materials. It allows the agency to use third party experts to update guidance on prescribing practices; and
- Directing the FDA to create a website to convey up-to-date information about the criteria for determining susceptibility of resistant organisms to drugs. It directs the creation of new criteria for determining susceptibility and gives the FDA authority to review the accuracy of devices intended to test for susceptibility.

Subtitle F: Medical Device Innovations (Secs. 3051-3060)
This subtitle was not scored by CBO

This subtitle establishes a new program to expedite the development and approval of breakthrough devices. In addition, it identifies five categories of medical software that generally will not be regulated as a medical device by FDA: 1) software that provides administrative support to health care facilities; 2) software used for maintaining or encouraging a healthy lifestyle and is unrelated

to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; 3) software that serves as electronic patient records (with restrictions); 4) software that supports transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results (with limitations); and 5) clinical decision support software. However, it would provide FDA with the authority to regulate software in these categories if the agency believes there is a reasonable likelihood of serious adverse health consequences. This subtitle also would:

- expand the applicability of the humanitarian device exemption;
- improve the ability of FDA to consider nationally or internationally recognized standards for device review purposes;
- expand patient access to point-of-care diagnostics by clarifying criteria for waiving Clinical Laboratory Improvement Amendment requirements; and
- require, as part of FDA's approval process, that manufacturers of certain reusable devices develop instructions and validation data regarding cleaning, disinfection, and sterilization.

Subtitle G: Improving Scientific Expertise and Outreach at FDA
(Secs. 3071-3076)
This subtitle was not scored by CBO

This subtitle includes various workforce provisions intended to improve the ability of FDA to recruit and retain outstanding and qualified scientific and technical experts.

Subtitle H: Medical Countermeasure Innovation (Secs. 3081-3088)
This subtitle was not scored by CBO

This subtitle aims to improve emergency preparedness and response through innovation in the development of medical countermeasures (MCMs) and other means. This includes:

- developing utilization guidelines for MCMs;
- clarifying contracting authority for the Biomedical Advanced Research Development Authority (BARDA);
- regularly updating budget plans for MCM priorities;
- permitting BARDA to enter into agreements with MCM Innovation Partners;
- streamlining Project Bioshield procurement;
- establishing a priority review voucher for drugs and vaccines for agents that represent national security threats;
- permitting the waiver of the Paperwork Reduction Act during a public health emergency; and
- clarifying FDA's authorities regarding the emergency use authorization.

Subtitle I: Vaccine Access, Certainty, and Innovation (Secs. 3091-3093)
Spends $4 million over 10 years

This subtitle aims to improve access to vaccines and encourage vaccine innovation by:

- requiring the CDC's Advisory Committee on Immunization Practices to make recommendations regarding new vaccines in a more timely and consistent way;
- requiring the Secretary of HHS, in consultation with relevant federal agencies and other stakeholders, to prepare and submit a report to Congress on vaccine innovation; and
- updating the vaccine injury compensation program related to maternal immunization.

Subtitle J: Technical Corrections (Secs. 3101-3102)
This subtitle was not scored by CBO

This subtitle makes technical corrections to the Food, Drug, and Cosmetic Act and strikes from law certain studies that have been completed.

TITLE IV: DELIVERY

This title includes a number of provision on health information technology (IT) policy, including interoperability, information blocking, patient matching, patient access to health information and telehealth. Specific provisions of interest include:

Assisting Doctors and Hospitals in Improving Quality of Care for Patients (Sec. 4001)
This provision was not scored by CBO

This section contains provisions aimed at reducing the documentation burden of using Electronic Health Records (EHRs). Specifically, the Secretary of HHS must establish a goal, strategy and recommendations to reduce the regulatory or administrative burdens related to the use of EHRs no later than one year after the date of enactment. The strategy will include incentives for the meaningful use of certified EHRs in the EHR Incentive Program, MIPS, and value-based programs; health IT certification; standards and implementation specifications; activities that provide individual access and activities related to protecting the privacy and security of electronic health information.

The bill allows physicians, to the extent consistent with state law, to delegate electronic medical record documentation requirements to a scribe if the physician has signed and verified the documentation.

It also states that the Secretary shall encourage, keep or recognize the voluntary certification of health IT for use in medical specialties and sites of service for

which no such technology is available. No later than 18 months from enactment, the Secretary shall make recommendations for the voluntary certification of health IT for use by pediatric health providers.

Lastly, the bill requires that the Secretary submit a report to the newly formed HIT Advisory Committee (see Sec. 4003) on attestation statistics for the EHR Incentive Programs that includes, among other things, state-level data on providers that have failed to attest.

Transparent Reporting on Usability, Security and Functionality (Sec. 4002)
This provision was not scored by CBO

This section places requirements on the developers of certified health IT products to provide greater information about these products. The Secretary, through notice and rulemaking, shall require as a condition of certification and maintenance of certification, that the health IT developer or entity: (i) does not take any action that constitutes information blocking, and (ii) provides satisfactory assurances that, unless for legitimate purposes specified by the Secretary, will not take action that may inhibit the appropriate exchange, access and use of electronic health information. The requirement prohibits health IT developers from restricting communication about the usability, interoperability, security, user experience or business practices of the developers related to exchanging electronic health information.

The provision requires the health IT developer to publish application programming interfaces (APIs) that allow health information from their products, including all data elements of the patient's EHR, to be accessed, exchanged and used without special effort. The health IT developer must also successfully test the health IT for interoperability in the setting in which the technology would be marketed.

Under this section, eligible professionals and hospitals in the Medicare EHR Incentive Program and eligible professionals in the Medicare Merit-Based Incentive Payment System (MIPS) will be exempt from payment adjustments if compliance with program requirements is not possible due to the decertification of EHR technology.

Lastly, the bill directs the Secretary to convene stakeholders to develop an EHR Reporting Program with reporting criteria about certified health IT products. Grantees to HHS shall develop reports that review health IT performance against the criteria. The reports will be distributed to the public.

Interoperability (Sec. 4003)
This provision was not scored by CBO

This section defines interoperability, sets forward steps for the creation of a trusted exchange framework and common agreement for sharing health information, and creates a new Health IT Advisory Committee to combine and replace the existing Health IT Policy and Standards Committees.

Interoperability. The term interoperability is defined to mean health IT that:

- enables secure exchange of electronic health information with use of electronic health information from other health IT without special effort on the part of the user.
- allows for complete access, exchange and use of all electronically accessible health information for authorized use under applicable state and federal law.
- does not constitute information blocking.

Trusted Exchange Framework. No later than six months after enactment, the bill directs the Office of the National Coordinator for Health IT (ONC) to convene stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. ONC, in collaboration with the National Institute of Standards and Technology (NIST) will provide technical assistance on the implementation of the trusted exchange framework and common agreement. ONC and NIST shall provide pilot testing of the trusted exchange framework and may delegate the testing activities to independent entities with appropriate expertise.

No later than one year after convening stakeholders, this provision requires ONC to publish the trusted exchange framework and common agreement. No later than two years after convening stakeholders and annually thereafter, ONC will publish a list of health information networks that adopted the common agreement and are capable of trusted exchange.

Federal agencies contracting or entering into agreements with health information exchange networks may require the networks to adopt the trusted exchange framework and common agreement. The statue will not require a health information network to adopt the trusted exchange framework or common agreement.

No later than three years after enactment, the Secretary must, directly or through partnership with a private entity, establish digital contact information for health professionals and health facilities. The Secretary may utilize an existing directory to make the digital contact information available. The index will ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

The Secretary will give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

The Health IT Advisory Committee. Under this provision, the Health IT Advisory Committee will replace the Health IT Policy and Health IT Standards Committees and unify their roles. The Health IT Advisory Committee will recommend a policy framework consistent with the ONC Strategic Plan, seek to prioritize achievement of the priority target areas specified for the Committee and may incorporate policy

recommendations made by the Health IT Policy Committee before the date of enactment. The HIT Advisory Committee also may identify additional priority target areas on a temporary basis, but the targets specified in the statute will be the focus of the work. ONC, in collaboration with the Secretary, will establish and update objectives and benchmarks for advancement of the priority target areas.

The provision requires the Health IT Advisory Committee to recommend standards, implementation specifications and certification criteria, including those developed, harmonized or recognized by the predecessor committee. Any recommendations it makes concerning interoperability must be consistent with the definition included in this legislation. The Committee will provide for the testing of such standards and specifications by NIST, as appropriate.
The Health IT Advisory Committee must have at least 25 members, representative of advocates for patients or consumers, providers, ancillary health care workers, purchasers, health plans, health IT developers, researchers, Federal agencies and individuals with expertise on health care quality, system functions, privacy, security and the electronic exchange and use of health information. Health IT Advisory Committee members will be limited to two three-year terms.

Information Blocking (Sec. 4004)
This provision was not scored by CBO

This section defines information blocking, sets forth mechanisms for reporting and investigation of information blocking actions, and establishes penalties for entities and individuals. The term information blocking does not include any practice or conduct occurring prior to the date that is 30 days after enactment.

Definition. The term information blocking is defined to mean a practice that:

- except as required by law or specified by the Secretary of HHS, is likely to interfere with, prevent or materially discourage access, exchange, or use of electronic health information; and
- if conducted by a health IT developer, exchange or network, such developer, exchange or network knows, or should know, that such practice is likely to interfere with, prevent or materially discourage the access, exchange or use of electronic health information; or
- if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent or materially discourage access, exchange, or use of electronic health information.

Information blocking practices may include:

- practices that restrict authorized access, exchange or use of information for treatment and other permitted purposes;
- health IT implementation in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging or using electronic health information; and

- implementing health IT in ways likely to lead to fraud, waste or abuse or impede innovations and advancements in health information access, exchange and use.

The Secretary, through rulemaking, must identify reasonable and necessary activities that do not constitute information blocking. The Secretary may consult with the Federal Trade Commission in promulgating regulations such that the regulations define practices that are necessary to promote competition and consumer welfare.

Investigations and Penalties. The HHS Inspector General may investigate any claim that a health IT developer, health care provider or health information exchange engaged in information blocking.

- with respect to health IT developers, networks and exchanges, individuals or entities that the Inspector General determines to have committed information blocking shall be subject to a civil monetary penalty which may not exceed $1,000,000 per violation.
- with respect to providers, any individual or entity the Inspector General determines to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives under applicable federal law, as determined through rulemaking.

ONC and OCR will issue guidance on common legal, governance and security barriers that prevent trusted exchange of electronic health information. ONC must provide a process for the public to report claims of information blocking.

Leveraging Electronic Health Records to Improve Patient Care (Sec. 4005)
This provision was not scored by CBO

This section requires certified EHRs to be capable of transmitting to, receiving and accepting data from registries, including clinician-led clinical data registries. In addition, health IT developers shall be treated as a provider for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health IT. No later than four years after enactment, the Secretary of HHS must submit to Congress a report concerning best practices and current trends voluntarily provided by patient safety organizations to improve the integration of health IT into clinical practice.

Empowering Patients and Improving Patient Access to their Electronic Health Information (Sec. 4006)
This provision was not scored by CBO

This section includes education and certification activities to increase patient access to their health information. Specifically, the Secretary, in coordination with the HHS Office for Civil Rights, is required to educate health care providers on ways of leveraging the capabilities of health information exchanges to provide patients with access to their electronic health information, clarify

misunderstandings by providers about using health information exchanges for patient access to electronic health information; and educate providers about health information exchanges. ONC and the Office of Civil Rights shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider.

In addition, ONC may require that certification criteria support: patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically; patient-reported information; and access to electronic health information for research at the option of the patient.

GAO Study on Patient Matching (Sec. 4007)
This provision was not scored by CBO

No later than one year after enactment, this provision requires the GAO to conduct a study to review policies and activities of ONC and other relevant stakeholders to ensure appropriate patient matching to protect patient privacy and security with respect to electronic health records and survey ongoing efforts in the private sector related to patient matching and their effectiveness. GAO will evaluate current methods used in certified EHRs for patient matching and determine whether ONC could improve patient matching by defining additional data elements, agree on a required minimum set of elements, and require EHRs to make certain fields required and use specific standards. The GAO must submit a report to Congress concerning their findings no later than two years after enactment.

GAO Study on Patient Access to Health Information (Sec. 4008)
This provision was not scored by CBO

This provision requires the GAO to review patient access to their own protected health information, including barriers to such access and complications or difficulties providers experience in providing access. This study will include consideration of how covered entities charge individuals, including patients, third parties and health care providers, for records requests, and other matters.

Medicare Pharmaceutical and Technology Ombudsman (Secs. 4011)
This section was not scored by CBO

This section creates a new Medicare pharmaceutical and technology ombudsman to address complaints, grievances, and requests from manufacturers relating to Medicare coverage, coding or payment related to new pharmaceutical, biotechnology, medical device and diagnostic products.

Medicare Site-of-Service Transparency (Secs. 4012)
Spends $6 million over 10 years

This provision requires the Secretary of HHS, beginning in 2018, to make available a searchable database that can be used to obtain information related to items and services furnished in hospital outpatient departments and ambulatory surgical centers, including the estimated payment amount and estimated beneficiary liability for the item or service. It provides CMS with $6 million to implement the provision.

Telehealth Services in Medicare (Secs. 4013)
This provision was not scored by CBO

This provision requires CMS and the Medicare Payment Advisory Commission (MedPAC) to provide information regarding the potential expansion of telehealth to the House and Senate committees of jurisdiction. CMS must provide information on the types of Medicare beneficiaries who could benefit from expanded telehealth services, testing of expanded telehealth by the Center for Medicare & Medicaid Innovation, high-volume services that might be appropriately provided via telehealth, and barriers to telehealth expansion. MedPAC must provide information on ways to expand Medicare coverage of telehealth to include services currently covered by private health plans. The legislation also includes a sense of the Congress that eligible telehealth originating sites should be expanded and that any expansion of telehealth services should meet or exceed the conditions of coverage and payment that would apply if the services were provided in person.

TITLE V: SAVINGS

Saves $6.2 billion over 10 years

The bill obtains about $6 billion in savings over 10 years. Specific provisions of interest include the following Medicaid-related sections that:

- move the implementation date up to Jan. 1 2018 for current law limits to Medicaid reimbursement for durable medical equipment. Reimbursement for durable medical equipment, prosthetics, orthotics, and supplies will be tied to Medicare reimbursement rates (saves $370 million over 10 years);
- require providers participating in Medicaid and Children's Health Insurance Program (CHIP) managed care to enroll with the state (saves $28 million over 10 years);
- require state Medicaid programs to provide beneficiaries in fee-for service (FFS) or primary care case management programs with an electronic provider directory (saves $13 million over 10 years);
- eliminate Medicaid federal matching funds for non-medically necessary prescription drugs used for cosmetic purposes or hair growth (saves $48 million over 10 years);

Other provisions in this section that save funds include those that:

- Reduce payments for Part B drugs that are infused through durable medical equipment, prosthetics, orthotics, and supplies (saves $660 million over 10 years);
- Reduce the amount in the Prevention and Public Health Fund (saves $3.461 billion over 10 years);
- Selling a portion of the Strategic Petroleum Reserve (saves $1.04 billion over 10 years);
- Rescinding a portion of the funds available to Territories to establish exchanges under the Affordable Care Act (ACA) (saves $464 million over 10 years);
- Establishing a new payment system for home infusion therapy suppliers (saves $372 million over 10 years).

TITLE VI THROUGH XIV: MENTAL HEALTH REFORMS

This section of the legislation reflects a bipartisan effort in Congress to address mental health reform. As passed, the legislation better prioritizes behavioral health within the Department of HHS by creating an Assistant Secretary for Mental Health and Substance Use, makes broad grant reforms, and includes numerous provisions to strengthen the behavioral health workforce, better train law enforcement, and improve mental health care parity and integration with physical health services, among other provisions. Key changes are highlighted below.

Title VI: Strengthening Leadership and Accountability (Secs. 6001-6031)
This title was not scored by CBO

This title establishes the position of Assistant Secretary for Mental Health and Substance Use, which will replace the current role of administrator for the Substance Abuse and Mental Health Services Administration. The Assistant Secretary's duties would expand from the administrator's and would specifically include working with stakeholders to develop and support activities to recruit and retain a workforce to address mental and substance use disorders. This title also creates a Chief Medical Officer (CMO) for the Substance Abuse and Mental Health Services Administration (SAMHSA), who will serve as a liaison with providers, among other duties, and requires the Assistant Secretary to develop and carry out a strategic plan for SAMHSA activities every four years.

Title VII: Ensuring Mental and Substance Use Disorders Prevention, Treatment and Recovery Programs Keep Pace with Science and Technology
(Secs. 7001-7005)
This title was not scored by CBO

Among other provisions, this title establishes a National Mental Health and Substance Use Policy Laboratory, charged with promoting evidence-based practices and innovation. It can award grants to states, local governments, Indian

tribes or tribal organizations, educational institutions and non-profits to develop evidence-based interventions to evaluate models that show promise or expand, replicate or scale evidence-based programs across wider areas.

Title VIII: Supporting State Prevention Activities and Responses to Mental Health and Substance Use Disorder Needs (Secs. 8001-8004)
This title was not scored by CBO

This title reauthorizes and makes changes to the Community Mental Health Services Block Grant and the Substance Abuse Prevention and Treatment Block Grant. It also allows states to submit a joint application for the block grants and permits the Assistant Secretary to waive application deadlines and compliance requirements in public health emergencies.

Title IX: Promoting Access to Mental Health and Substance Use Disorder Care (Secs. 9001-9033)
This title was not scored by CBO

This title primarily establishes, reauthorizes, and/or updates various behavioral health-related grant programs, such as those aimed at integrating primary and behavioral health care; preventing suicide; providing mental health and substance use disorder treatment services for homeless individuals; supporting education and training of the behavioral health workforce; and more. Certain current grant programs considered to be outdated are removed. This title also changes a program that helps designate hospitals as Emergency Mental Health Centers. The program will now enhance community-based crisis response systems and help states develop and maintain databases of beds at treatment facilities. It further requires the continuation of the National Suicide Prevention Lifeline Program; establishes a Minority Fellowship Program; and includes several provisions focused on behavioral health services on college campuses.

Title X: Strengthening Mental and Substance Use Disorder Care for Children and Adolescents (Secs. 10001-10006)
This title was not scored by CBO

This title includes provisions focusing on community mental health services for children with a serious emotional disturbance, children's recovery from trauma, screening and treatment for maternal depression, and more. It establishes a new grant program to promote behavioral health integration in pediatric primary care by supporting statewide or regional pediatric mental health care telehealth access programs, among other provisions.

Title XI: Compassionate Communication on HIPAA (Secs. 11001-11004)
This title was not scored by CBO

These provisions require that, within a year of issuing final regulations pertaining to confidentiality of alcohol and drug abuse health records, the Secretary must convene relevant stakeholders to determine the effect of the regulations on

patient care, health outcomes and patient privacy. Further, through the Office of Civil Rights, the Secretary of HHS must ensure that health care providers, professionals, patients, families, and others have adequate resources relating to appropriate uses and disclosures of protected health information under the Health Insurance Portability and Accountability Act (HIPAA). The Secretary also will have one year to issue guidance clarifying the circumstances in which a health care provider or covered entity may use or disclose protected health information under HIPAA. In addition, the Secretary must identify and disseminate model programs and materials to train providers and patients about permitted uses and disclosures of health information and the right to protect and obtain information.

Title XII: Medicaid Mental Health Coverage (Secs. 12001-12006)
Saves $5 million over 10 year

This title clarifies that Medicaid allows separate payment for the provision of primary care and mental health services at a facility on the same day. It specifies that children receiving Medicaid inpatient psychiatric services are also eligible for the full range of early, and periodic screening, diagnostic, and treatment services (EPSDT) as of Jan.1 2019. EPSDT services require state Medicaid programs to cover and treat any condition that is discovered during an EPSDT screen. This title also requires a study and report to Congress about coverage of services provided through Medicaid managed care organizations or prepaid inpatient health plans with respect to individuals over the age of 21 and under the age of 65 for the treatment of mental health disorders in institutions for mental disease. Further, CMS will be required to issue guidance to state Medicaid Programs about opportunities to design innovative service delivery systems for adults with a serious mental illness or children with a serious emotional disturbance. The guidance must include opportunities for section 1115 demonstration projects, which could provide much greater flexibility for states to cover patients in other settings such as Institutions for Mental Disease. CMS must also issue a report to Congress about the Medicaid Emergency Psychiatric Demonstration Project, among other provisions.

Title XIII: Mental Health Parity (Secs. 13001-13007)
This title was not scored by CBO

Among numerous provisions supporting parity protections, this title requires several federal agencies to develop a compliance program guidance document to help improve compliance with mental health parity requirements. It also states that if the Secretary of HHS, Labor, or Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated mental health parity laws at least five times, the relevant Secretary must audit the plan documents for the health plan or issuer.

Title XIV: Mental Health and Safe Communities (Secs. 14001-14029)
This title was not scored by CBO

This title includes provisions of legislation introduced in the Senate that aim to improve the interaction between individuals with mental illness and law enforcement and the criminal justice system. Various provisions would allow federal funds (either newly authorized or existing grant programs) to be used to better train law enforcement for situations involving individuals with mental illness (including crisis de-escalation), conduct behavioral health risk and needs assessments for individuals in the criminal justice system, provide mental health and transitional services for individuals who are re-entering the community, and much more.

TITLE XV: PROVISIONS RELATING TO MEDICARE PART A

The Act makes a number of changes to policies under Part A of the Medicare program, including to the Hospital Readmissions Reduction Program and long-term care hospital (LTCH) policies. Specific provisions of interest include:

Development of Medicare Study for HCPCS Versions of MS-DRG Codes for Similar Hospital Services (Sec. 15001)
No impact on spending

The bill requires, no later than Jan. 1, 2018, the creation of a crosswalk between HCPCS codes (outpatient) and ICD-10-PCS codes (inpatient) for no fewer than 10 surgical Medicare-Severity diagnosis-related groups (MS-DRGs). CMS will be required to develop a HCPCS MS-DRG definitions manual and software for ICD-10-PCS codes for these 10 DRGs. It will be posted on the CMS website and available for public use/redistribution without charge. In doing this, Sec. 15001 indicates that CMS should consult with MedPAC and consider the MedPAC analysis related to short inpatient stays.

Establishing Beneficiary Equity in the Medicare Hospital Readmission Program (Sec. 15002)
No impact on spending

The legislation requires CMS to make an adjustment to the Hospital Readmissions Reduction Program (HRRP) to account for the socioeconomic status of patients in a hospital's community. Starting in FY 2019, CMS will be required to make a "transitional adjustment" in which it assigns each hospital to groups based on the proportion of patients dually eligible for Medicare and Medicaid, and compares each hospital's performance to others within its dual-eligible grouping. In developing the transitional adjustment approach, the agency will be required to consult with MedPAC. After this transitional adjustment, which the AHA expects would be used for at least two fiscal years (FYs 2019 and 2020), CMS could modify the adjustment approach. A modified approach must take into account the findings of the two reports on socioeconomic adjustment in Medicare

mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014.

Other requirements include:

- Budget-neutral implementation of socioeconomic adjustment;
- By June 2018, a MedPAC report to Congress that assesses whether changes in readmission performance are related to changes in the utilization of outpatient and emergency department services;
- Starting in FY 2018, a requirement that CMS assess whether it can use V-codes and other ICD codes to exclude non-compliant patients from the calculation of readmissions performance; and
- Starting in FY 2018, a requirement that CMS assess whether it should exclude burns, trauma, psychosis, end-stage renal disease and substance abuse patients from the calculation of hospital readmission performance.

Five-year Extension of the Rural Community Hospital (RCH) Demonstration Program (Sec. 15003)
Saves $21 million over 10 years

This provision extends the RCH Demonstration for an additional five years and expands the program to rural areas in all states. This program, which allows rural hospitals with fewer than 51 acute care beds to test the feasibility of cost-based reimbursement, was established under the Medicare Prescription Drug, Improvement and Modernization Act. The ACA extended the program an additional five years, increased the maximum number of participating hospitals from 15 to 30, and expanded the eligible sites to rural areas in 20 states with low population densities. Under this bill, the ACA limit for the maximum number of participating hospitals – 30 – would remain in place. The legislation also would require a report to Congress evaluating the impact of the demonstration be submitted no later than Aug. 1, 2018.

Regulatory Relief for LTCHs (Sec. 15004)
Impact is less than $50 million over 10 years

Retroactive to April 1, 2014, the bill expands exceptions that currently apply to new LTCH hospitals or satellites to al include expansions of LTCH beds in an existing LTCH. This moratorium and its exceptions were originally established under the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) and later amended by the Pathway for SGR Reform Act of 2013 and the Protecting Access to Medicare Act of 2014.
This expansion is offset by a cut related to the outlier pool. Specifically, for FY 2018 and beyond, LTCH rates will be reduced to reflect an 8-percent high-cost outlier pool, although this is the amount of the current pool. However, when setting the high-cost outlier threshold, a 7.975 percent pool will be used. This reduced pool will produce a higher threshold, which will lower the number of

cases that qualify for a high-cost outlier payment. This provision will not affect site-neutral payments.

Savings from IPPS MACRA Pay-for Through Not Applying Documentation and Coding Adjustment (Sec. 15005)
Saves $760 million over 10 years

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) spread the restoration of coding cuts required by the American Taxpayer Relief Act of 2012 over six years. Specifically, it restored 3.0 percentage points over a six-year period by adding 0.5 percentage point to the inpatient hospital update in each of FYs 2018 through 2023. This section implements a cut of 0.041 percentage points in FY 2018 to this amount to offset the changes to Section 603 of the Bipartisan Budget Act of 2015, discussed below. As a result, the Inpatient PPS increase set forth in MACRA would be adjusted to be an increase of 0.4588 percentage points rather than 0.5 percentage points for FY 2018.

Extension of Certain LTCH Medicare Payment Rules (Sec. 15006)
Sections 15006-15010 in total spend $58 million over 10 years

The 25% Rule regulation applies a payment penalty to certain LTCH cases that exceed a threshold established for each of its referring hospitals. Congress has provided relief from full implementation of the 25% Rule since passage of the MMSEA of 2007 through 2016. This provision would extend this relief for LTCH discharges from October 1, 2016 through September 30, 2017.

Application of Rules on the Calculation of Hospital Length of Stay to all LTCHs (Sec. 15007)
See score above

Currently, for LTCHs established through Dec 26, 2013, the 25-day average length of stay is calculated without Medicaid Advantage and LTCH site-neutral cases. Under this provision, this exclusion from the methodology would also apply to LTCHs that began operations after December 26, 2013.

Change in Medicare Classification for Certain Hospitals (Sec. 15008)
See score above

This provision codifies regulatory changes pertaining to the sole “cancer LTCH” related to its unique payment under the Tax Equity and Fiscal Responsibility Act of 1982.

Temporary Exception to the Application of the Medicare LTCH Site-neutral Provisions for Certain Spinal Cord Specialty Hospitals (Sec. 15009)
See score above

This section waives site-neutral payment rates for cost reporting periods beginning in FYs 2018 and 2019 for certain LTCHs. Qualifying LTCHs must be

not-for-profit and have existed since June 1, 2014. In addition, they must primarily provide treatment for catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions, with at least 50 percent of cases in qualifying MS-LTC-DRGs. Qualifying LTCHs must also have "significant out-of-state admissions."

Temporary Exception to the Application of the Medicare LTCH site-neutral Provision for Certain Discharges with Severe Wounds (Sec. 15010)
See score above

This provision waives site-neutral payment rates for cost reporting periods beginning in FY 2018 for severe wound cases treated by "grandfathered LTCHs."

TITLE XVI: PROVISIONS RELATING TO MEDICARE PART B

The Act makes a number of changes to policies under Part B of the Medicare program, including to how new, off-campus hospital outpatient departments will be paid under the Outpatient Prospective Payment System (OPPS). Specific provisions of interest include:

Continuing Medicare Payment Under Outpatient Prospective Payment System (OPPS) for Services Furnished by Mid-build Off-campus Outpatient Departments of Providers (Sec. 16001)
Spends $760 million over 10 years

This provision revises Section 603 of the Bipartisan Budget Act of 2015 to move the grandfather date for off-campus hospital outpatient departments (HOPDs) under development from Nov. 2, 2015 to 60 days after the law is enacted, as long as the HOPD was under development prior to Nov. 2, 2015. Current law reimburses grandfathered facilities at the OPPS rate, while new facilities are paid at a lower rate under another Part B payment system. This provision would allow HOPDs that narrowly missed the November 2015 deadline for furnishing covered outpatient department services, but already have opened or will soon open, to qualify for the higher OPPS rate.

Specifically, for purposes of items and services furnished in 2017, if CMS received an attestation (as described in 42 CFR 413.65(b)(3)) from a hospital prior to Dec. 2, 2015 indicating that their department was a provider-based department of the hospital, the HOPD would be fully grandfathered, even if they were not providing covered outpatient department services and billing Medicare under the OPPS before Nov. 2, 2015.

The bill also describes an alternative exception that would impact payments for items and services furnished in 2018 and beyond. Under this alternative exception, an HOPD would be grandfathered if:

- CMS received an attestation from the hospital prior to 60 days after the law was enacted, indicating that its HOPD was a provider-based department of the hospital;
- the provider properly updated its Medicare enrollment form to include the HOPD; and
- prior to Nov. 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of the HOPD (referred to in the bill as the "mid-build requirement") and the Secretary of HHS receives from the hospital's CEO or COO a written certification that the HOPD met the mid-build requirement no later than 60 days after the law was enacted.

In addition, CMS would audit each of the HOPDs that were grandfathered under the alternative exception for compliance with these provisions by Dec. 31, 2018.

Treatment of Cancer Hospitals in an Off-campus Outpatient Department of a Provider (Sec. 16002)
No impact on spending

Under this section, a new off-campus HOPD of a dedicated cancer center would receive an exemption from the site-neutral payment changes in Section 603 of the Bipartisan Budget Act (BiBA) of 2015 and would be able to bill under the OPPS if:

- For departments of dedicated cancer centers that became HOPDs between Nov. 2, 2015 and Dec. 7, 2016, CMS receives from the center an attestation by Feb. 5, 2017 of this bill.
- For departments of such a dedicated cancer center that became HOPDs after Dec. 7, 2016, CMS receives from the center an attestation within 60 days of the department becoming an HOPD.

CMS will be required to audit the HOPDs of these dedicated cancer centers for compliance with these provisions within two years of the date that it receives the attestation. To fully offset the cost of this exemption, the bill requires CMS to reduce the dedicated cancer centers' target payment-to-cost ratio adjustment by at least 1 percentage point.

Treatment of Eligible Professionals in Ambulatory Surgical Centers (ASCs) for Meaningful Use and MIPS (Sec. 16003)
Spends $17 million over 10 years

This section protects eligible professionals that deliver substantially all of their care in ambulatory surgical centers from cuts under the Medicare EHR Incentive Program in 2017 and 2018. Protections continue under MIPS until three years after the Secretary of HHS determines, through rulemaking, that certified EHRs are available for the ASC setting.

Continuing Access to Hospitals Act of 2016 (Sec. 16004)
No impact on spending

This provision prohibits CMS from enforcing the "direct supervision" regulations for calendar year 2016 for outpatient therapeutic services provided in critical access hospitals and certain small, rural hospitals. It also requires the MedPAC to submit a report to Congress analyzing the effect of this enforcement prohibition on the access to health care by Medicare beneficiaries, the economic impact on hospitals, the impact upon hospital staffing needs, and the quality of health care furnished to such beneficiaries.

Delay in Authority to Terminate Contracts for Medicare Advantage (MA) Plans Failing to Achieve Minimum Quality Ratings (Sec. 17001)
Saves $20 million over 10 years

This provision prohibits CMS from terminating an MA plan contract solely as a result of poor performance on the MA star ratings program through the 2018 plan year. During this time, HHS would be required to continue to study and request stakeholder input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage star ratings.

Requirement for Enrollment Data Reporting for Medicare (Sec. 17002)
No impact on spending

This section requires that the Secretary of HHS report to Congress Medicare enrollment data broken down by enrollment type (e.g., original Medicare or MA) by Congressional district and state.

Updating the Welcome to Medicare Package (Sec. 17003)
No impact on spending

This provision directs the Secretary of HHS to update the information included in the Welcome to Medicare package to include information about options for receiving benefits under the Medicare program, i.e., through the original Medicare program, through MA and/or through prescription drug plans. It also directs the Secretary to seek stakeholder input on information included in the Welcome to Medicare package within six months of enactment.

Preservation of Medicare Beneficiary Choice Under MA (Sec. 17005)
Spends $95 million over 10 years

This section allow Medicare beneficiaries enrolled in MA plans the opportunity to switch plans or return to the original Medicare program one time during the first three months of enrollment.

Allowing End-stage Renal Disease (ESRD) Beneficiaries to Choose an MA Plan (Sec. 17006)
No impact on spending

This section allows individuals with ESRD the choice of enrolling in an MA plan or receiving their benefits through the original Medicare program. The Secretary of HHS would exclude from the MA payment rates the cost of acquiring kidneys, which would be separately reimbursed on a fee-for-service basis. The bill also directs the Secretary to evaluate whether the MA star rating program should be updated to incorporate a measure related to ESRD. Finally, this section makes a number of changes to the law with respect to the MA risk adjustment model, including directing the Secretary to use two years of diagnostic data, to take into account the total number of diagnoses an enrollee has, and to take into account whether a beneficiary is dually eligible for Medicaid, among other changes. It also directs the Secretary to evaluate potential revisions to the risk adjustment model to account for mental health and substance use disorders and the incorporation of newly enrolled ESRD populations.

Exception from Group Health Plan Requirements for Qualified Small Employer Health Reimbursement Arrangements (Sec. 18001)
Spends $363 million over 10 years

This section allows small employers with less than 50 employees the option of directly reimbursing health care expenses up to a certain amount ($4,950 for individuals and $10,000 for families) to meet requirements related to provision of affordable coverage if their employees purchase creditable coverage on their own. Previously, small employers could only offer direct reimbursement of expenses if they provided it in conjunction with a group coverage policy. Under this section, employees in such arrangements would not be eligible for the full federal advanced premium tax credit to purchase coverage on the marketplaces.

FURTHER QUESTIONS

If you have questions, please contact AHA Member Relations at 1-800-424-4301.