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ANALYSIS OF THE HEALTH CARE REFORM LAW: PPACA AND THE RECONCILIATION ACT

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). On March 30, 2010, the Health Care and Education Reconciliation Act was enacted, the reconciliation law that made changes to the PPACA. After 18 months of legislative activity, preceded by decades of fits and starts, a major step forward was taken in reforming the country's health care system. Health care reform offers coverage for the majority of uninsured individuals in the United States and eventually will add up to 16 million individuals to the Medicaid program.

The National Health Law Program (NHeLP) analysis includes the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148) as well as the amendments made to PPACA by the Health Care and Education Reconciliation Act (Recon. Act, P.L. 111-152). For those of you who are looking for an integrated version of the PPACA, including the Manager's Amendment and the Reconciliation Act, an unofficial version is available at http://s3.amazonaws.com/thf_media/2010/pdf/ppaca-consolidated.pdf.

NHeLP has undertaken a comprehensive analysis of these laws. Given NHeLP's focus on Medicaid and CHIP, civil rights, reproductive health and justice, and empowering low-income beneficiaries and their advocates, we have concentrated our analysis on areas of the law most related to those areas and populations.

The Table of Contents identifies the sections that have been analyzed. In addition to this broad analysis, NHeLP will release more in-depth analyses on specific topics. We anticipate that these focused stand-alone analyses will cover topics such as Medicaid, children's health, health care disparities, reproductive health and health care for immigrants.

The analysis primarily focuses on Titles I and II of the law. We have divided the document into three parts:

- Part I includes an analysis of PPACA Title I, covering the private insurance reforms and state-based exchanges;
- Part II includes an analysis of PPACA Title II, covering changes to the Medicaid program; and
- Part III analyzes selected provisions from Titles III, IV, VI, XIII and IX.

Notes

When reading this analysis, "Secretary" generally refers to the Secretary of the Department of Health and Human Services, unless specifically noted otherwise.

A few other notes and abbreviations are relevant to this analysis:

Abbreviations of Laws:

- SSA refers to the Social Security Act
- PHSA refers to the Public Health Service Act, 42 U.S.C. § 300gg et seq.
- DRA refers to the Deficit Reduction Act
- CHIPRA refers to the Children's Health Insurance Program Reauthorization Act
- IRC refers to the Internal Revenue Code of 1986

Abbreviation of Terms:

- FMAP refers to the Federal Medical Assistance Percentage
- FPL refers to the Federal Poverty Level
- LIS refers to the Low Income Subsidy for Medicare Part D

Abbreviation of Federal Agencies or other Organizations:

- DHS – Department of Homeland Security
- SSA – Social Security Administration
- Treasury – Department of the Treasury
- NAIC – National Association of Insurance Commissioners

We have generally included effective dates for each section. However, it is important to recognize that many provisions will not be implemented without appropriations. Thus, the appropriations process is critical to ensuring that many of the Act's important provisions can be implemented.

If you have any questions about the analysis or need further information, please call NHeLP at (202) 289-7661, or e-mail Mara Youdelman at Youdelman@healthlaw.org.

And finally, much thanks to the NHeLP staff – in particular Mara Youdelman – who worked tirelessly to complete this analysis:

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We hope you find this analysis useful.

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TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

Only the following sections are analyzed

Subtitle A—Transforming the Health Care Delivery System

PART II—NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY

Sec. 3011. National strategy.

PART III—ENCOURAGING DEVELOPMENT OF NEW PATIENT CARE MODELS

Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS.
Sec. 3022. Medicare shared savings program.
Sec. 3023. National pilot program on payment bundling.
Sec. 3024. Independence at home demonstration program.
Sec. 3025. Hospital readmissions reduction program.
Sec. 3026. Community-Based Care Transitions Program.
Sec. 3027. Extension of gainsharing demonstration.

Subtitle B—Improving Medicare for Patients and Providers

PART III—IMPROVING PAYMENT ACCURACY

Subtitle C—Provisions Relating to Part C

Sec. 3201. Medicare Advantage payment.
Sec. 3202. Benefit protection and simplification.
Sec. 3203. Application of coding intensity adjustment during MA payment transition.
Sec. 3204. Simplification of annual beneficiary election periods.
Sec. 3205. Extension for specialized MA plans for special needs individuals.
Sec. 3206. Extension of reasonable cost contracts.
Sec. 3207. Technical correction to MA private fee-for-service plans.
Sec. 3208. Making senior housing facility demonstration permanent.
Sec. 3209. Authority to deny plan bids.
Sec. 3210. Development of new standards for certain Medigap plans.

Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans

Sec. 3301. Medicare coverage gap discount program.
Sec. 3302. Improvement in determination of Medicare part D low-income benchmark premium.
Sec. 3303. Voluntary de minimis policy for subsidy eligible individuals under prescription drug plans and MA–PD plans.
Sec. 3304. Special rule for widows and widowers regarding eligibility for low-income assistance.

TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

National Strategy to Improve Health Care Quality, PPACA §§ 3011, 10302

This provision adds new § 399H to the Public Health Service Act.[1] The new section requires HHS to develop and implement a national strategy to improve the delivery of health care and patient health outcomes through a transparent collaborative process. It must identify priorities and establish a strategic plan to achieve the priorities. The national strategy must be developed and submitted to the relevant committees of Congress no later than January 1, 2011.

The national strategy must be updated at least annually. Any update must include:

- a re-evaluation of short- and long-term goals;
- an analysis of the progress or lack of progress, and/or any barriers that were encountered; and
- information required to be reported by child health quality measures for children enrolled in Medicaid and the Children's Health Insurance Program at 42 U.S.C. 1320b-9a.

In addition, this section requires the development of a Health Care Quality Website to be operational by January 1, 2011, so that the national strategy, specific agency plans and anything else determined by the Secretary of HHS may be available to the public.

This section sets out nine requirements the priorities must meet. They include:

- having the greatest potential to increase health outcomes, efficiency and patient-centered care for all populations, including the needs of children and vulnerable populations;
- identifying areas of health care delivery that may have the potential for rapid improvement in the quality and efficiency of care;
- addressing gaps in quality, efficiency, comparative effectiveness information,[2] health outcomes and data aggregation techniques;
- enhancing the use of health care data to improve quality, efficiency, transparency and outcomes;
- addressing the health care provided to persons who have high-cost chronic conditions; and
- reducing health disparities across disparity populations.

This national strategy provides an opportunity for a range of stakeholders to participate in this transparent collaborative process to help shape the priorities, goals, and activities to address critical quality of care issues that impact people's lives every day – with an emphasis on patient-centered care and addressing health care disparities.

[1] Amending 42 U.S.C. § 241 *et seq*, adding § 399HH, to a new Part S – Health Care Quality Programs, Subpart I – National Strategy for Quality Improvement in Health Care.

[2] Taking into account the limitations established on comparative effectiveness research in PPACA § 6301(c) which adds to the Social Security Act new § 1182 (c) and (d).

Effective date: March 23, 2010.

Establishment of Center for Medicare and Medicaid Innovation ("CMI") Within CMS, PPACA §§ 3021, 10306

This provision creates a new entity within CMS that will be responsible for testing innovative payment and delivery models to reduce program costs while maintaining or improving quality. The CMI applies to Medicaid, Medicare and CHIP, and must be operational by January 2011. The Secretary is empowered to select the models to be tested. The statute lists examples of models that could be tested (titled "opportunities," and listed in more detail below), and factors the Secretary should consider in selecting models, although the Secretary is not limited to selecting these models or using these factors. The opportunities and factors focus heavily on improving consumer access and quality. Testing can be limited to certain geographic areas. The provision is added to Title XI of the Social Security Act as § 1115A.

The provision specifically waives a budget neutrality requirement for an "initial period" but requires termination or modification of a model if improvement or maintenance of quality and reduction or maintenance of costs is not achieved. If the model is successful, the Secretary may expand the model as widely as nationally. (Note: this provision does allow continuation and expansion if quality improves and spending remains constant.) Expansion is not allowed if coverage or benefits would be denied or limited by the model. The Secretary is required to evaluate all models tested, and those results must be made publically available. The Secretary must also make a report to Congress at least yearly.

Some of the "opportunities" listed in the law, and some of the likely models the CMI will explore, will approximate "bundled" care. Please see our analysis of *General Concerns Regarding Bundled Care*, under § 3023.

The CMI is required to consult with government and medical experts, but not consumers. However, the CMI is required to "use open door forums or other mechanisms to seek input from interested parties." The CMI should be explicitly required to consult with consumers and their representatives in deciding whether and how to implement different innovations. In addition, for entities with whom the CMI has an advisory relationship, and which could be providing biased information or advancing particular interests, regulations should specifically apply conflict of interest, disclosure, and recusal requirements for advisory roles.

The long list of "Opportunities"[3] provides examples of models to be tested, which include many options that may be of interest to consumer advocates:

- payment reform in primary care, including medical homes, payment bundling and salary-based payment;
- direct medical contracting, including bundling and salary-based payment;
- geriatric assessments and care plans;
- salary-based payment;

[3] *See* new § 1115A(b)(2)(B).

- care coordination through HIT, disease registries and telehealth;
- diagnostic imaging payment based on clinical adherence;
- medication management;
- community support teams for medical homes;
- patient decision support tools;
- integration for dual eligibles;
- all payer reform;
- cancer treatment payment based on clinical adherence;
- continuing care hospitals for post-acute care;
- home health provider chronic care management;
- collaboratives of health institutions;
- electronic monitoring of inpatient care;
- specialty care without referrals;
- health care innovation zones combining bundled care and teaching functions;
- telehealth; and
- care coordination in rural and urban areas.

In addition, the factors for selecting models also include important consumer priorities, such as preference for models that enhance quality improvement and patient centeredness.

The CMI's fundamental purpose, as generally stated[4] and as applied in the model selection process,[5] is to reduce costs while preserving or enhancing quality. As in other sections of PPACA, the overriding purpose is to reduce costs (e.g. could the Secretary initiate evaluation of a model that is expected to increase quality but not reduce costs). However, in more specific language addressing the continuation or explanation of models (rather than initiation), models can be continued and expanded if they improve health quality but maintain costs. Therefore, there could be disagreement as to whether cost reduction and quality improvement are equal objectives of the CMI, and this should be clarified through regulation.

This section includes broad authority for the Secretary to waive specified requirements of the Social Security Act, including Title XI,[6] Title XVIII (Medicare), and select parts of Title XIX (Medicaid), for the purpose of testing models. The waivers of authority for Title XIX include authority to waive requirements for statewideness, a public process for hospital and institutional rate-setting, and some regulation of managed care organizations.

This section also includes a broad provision limiting administrative and judicial review of many features of this section, including:

- selection of models for testing;
- selection of participants for testing;
- parameters and duration of testing;

[4] In newly created Social Security Act §1115(a)(1).
[5] In newly created Social Security Act §1115(b)(2).
[6] Title XI is titled "General Provisions, Peer Review, and Administrative Simplification", and most importantly in this context, contains authority for demonstration projects at §1115.

- determinations regarding budget neutrality;
- termination or modification of a tested model; and
- determinations about expansion of duration or scope of a model.

Implementation Date: January 1, 2011.

Medicare Shared Savings Program, PPACA §§ 3022, 10307

This provision requires the Secretary to create Accountable Care Organizations (ACOs) in the Medicare program by January 2012.[7] The provision adds new § 1899 to the SSA. ACOs would be organized groups of medical providers that would manage the care of selected fee-for-service Medicare beneficiaries. The ACO would be required to meet performance standards and functions specified in the statute, subject to Secretarial approval, and would be permitted to share some of the savings generated by the care management among the medical providers that form the ACO. ACOs can also be paid by a partial capitation model or other payment models at the Secretary's discretion, although these models may not result in additional program expenditures. Many of the criteria the ACO must meet are designed to promote patient access and quality. The Secretary will also develop quality measures and reporting requirements for ACOs, as well as a process to assign fee-for-service Medicare beneficiaries to ACOs. The statute does give the Secretary authority to sanction or terminate an ACO that avoids at-risk[8] patients, or to terminate an ACO that does not meet quality standards. Until the program under this section is in effect, the Secretary may contract with ACOs under the demonstration in § 1866A of the Social Security Act, which allows testing of incentives for medical provider groups.

The Accountable Care Organizations created by the provision may deliver a form of "bundled" care or could utilize other payment models that create similar incentives. Please see our analysis of *General Concerns Regarding Bundled Care*, under section 3023.

It's not clear if smaller medical providers will be able to draw together the medical resources to form ACOs, including providers (such as specialists) and administrative resources. It seems likely that ACOs will be formed in areas dominated by large health systems.

The law clearly authorizes the Secretary to determine how to assign Medicare fee-for-service enrollees to ACOs. This raises particular bundling concerns referenced below in § 3023, such as questions as to what choice consumers will have in the process,[9] what kind of notice they will receive and what alternatives to the ACO consumers will have. There are also continuity concerns such as:

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[7] This section only authorizes ACOs in Medicare, but ACOs are also authorized for Medicaid in PPACA § 2704 and § 2706. See also PPACA § 2705.

[8] PPACA does not define "at-risk" or explain how this will be determined, other than by Secretarial discretion. But for those ACOs receiving capitated rates, the capitated rates could otherwise directly or indirectly incentivize ACOs to enroll only the healthiest patients and not those "at risk" who may include patients with a history or disparities or circumstances or conditions that could lead to higher costs for the ACO (e.g. limited English proficient patients who need interpreters).

[9] The Medicare 'Freedom of Choice' provision in § 1802 of the Social Security Act gives Medicare enrollees the right to choose their Medicare providers.

- when enrollees are assigned to an ACO, does that mean the consumers will see a rupture with all of their current medical providers;
- if an enrollee's current providers choose to participate in an ACO, will the enrollees be forced to participate in the ACO or can they continue to see their providers as fee-for-service enrollees;
- what if an enrollee has two primary providers, but those providers are not both in an ACO, or the same ACO.

This section includes broad authority for the Secretary to waive specified requirements of the Social Security Act, including selects parts of Title XI[10] and all of Title XVIII (Medicare), to carry out the purposes of this section. The waivers of authority for Title XI include authority to waive requirements for civil and criminal penalties.

This section also includes a broad provision limiting administrative and judicial review of many features of this section, including:

- criteria for quality performance standards;
- assessments of care quality;
- assignment of beneficiaries to ACOs;
- determinations related to shared savings eligibility for an ACO;
- percentages and limits to shared savings payment; and
- termination of ACOs.

Implementation Date: By January 1, 2012.

National Pilot Program on Payment Bundling, PPACA §§ 3023, 10308

This provision creates a Medicare pilot program on hospitalization payment bundling to improve care quality, coordination and efficiency. It adds new section 1866D the SSA. The pilot is to be started by January 2013 for a period of five years. Each bundle is time-limited, specifically organized around hospitalizations, and defines an episode of care as the hospitalization plus three days pre- and 30 days post-hospitalization. The hospitalization must be for one of a limited set of conditions to be identified by the Secretary, based on factors[11] set out in the statute, and the services[12] eligible for bundled payment are specifically set out in statute. Eligible Medicare beneficiaries include individuals with Parts A or B, but not Part C or PACE.[13]

[10] Title XI is titled "General Provisions, Peer Review, and Administrative Simplification".
[11] Factors for conditions to be selected include: whether they include a mix of chronic and acute conditions; include a mix of surgical and medical conditions; have potential to improve care while reducing spending; have variations in re-admission rates or post acute expenditures; are high-volume and have high post-acute expenditures;, and whether the Secretary considers they are amendable to bundling.
[12] Applicable services include: acute care inpatient services; outpatient physician's services; outpatient hospital services; post-acute care services; and other services deemed appropriate by the Secretary.
[13] PACE, the Program of All-Inclusive Care for the Elderly, is a program available to Medicare beneficiaries who have a nursing home level of care need, and provides a comprehensive service package which helps beneficiaries remain at home instead of being institutionalized.

In conducting the pilot, the Secretary must also pilot test the continuing care hospital model. Continuing care hospitals are hospitals that meet patient quality standards and provide inpatient rehabilitation facility level services under common management.[14]

The Secretary is required to consult with quality agencies[15] and develop an assortment of patient quality survey tools. After January 2016, the Secretary can expand the scope or duration of the pilot if the Secretary determines the pilot will improve or maintain quality while reducing costs and not harm coverage of benefits for consumers, and the CMS Chief Actuary determines it would reduce spending. The Secretary will also develop participation requirements for providers and a provider payment methodology, which must include payment for patient-centered activities. The provision also requires quality reporting, including the use of electronic health records.

This section includes broad authority for the Secretary to waive specified requirements of the Social Security Act, including Title XI[16] and Title XVIII (Medicare), for the purpose of carrying out pilot programs.

General Concerns Regarding Bundled Care

Providers will receive fixed "bundled" payments for the patients they treat. The bundled payments will cover all the costs of covered care rather than a provider billing for each item or service provided. Bundling creates numerous incentive problems and concerns, which must be addressed:

- risk adjustment – unless there is risk adjustment, providers will have an incentive to only accept patients who are likely to be low utilizers of care, because providers will only get a flat fee yet be liable for paying for all utilization by the covered patients;
    - one solution is to exclude from the bundled payment certain services foundational to care coordination, such as an initial assessment, development of a care plan, regular updating of the care plan, specific care coordination actions (making follow-up appointments, arranging interpreters, referrals for assessments to HCBS programs post-discharge, etc.), and discharge planning;
    - another option is to risk adjust based on demographics so that patients do not suffer inequities in care based on geography or demographics, and data collection, monitoring, and stratified reporting of quality measures can help mitigate this;
- denials of care:
    - providers may have an incentive to deny care once a consumer is enrolled in a bundle, because every service they provide is a cost drawn from the flat fee they have already received;
    - providers who are treating the patient would be the ones who stand to gain financially by "denying" care;

[14] *See* PPACA §10308(a)(3).
[15] Namely, the Agency for Healthcare Research and Quality and the Social Security Act §1890(a) contractor (currently National Quality Forum).

[16] Title XI is titled "General Provisions, Peer Review, and Administrative Simplification".

- timing – the "episode of care" may exacerbate the incentive around denying care, because providers have an incentive to delay care until after the episode ends, when they are no longer responsible for providing care;
- quality measures – the design must not disfavor complex patients, such as patients who cannot improve and for whom the optimal result might be maintenance of health status, maximization of function or simply slowing of deterioration; and
- patient-centeredness – will patients be included in the decisions about participation in bundled care, whether they will have notice and choice in the decision, and how their capacity to consent will be evaluated;

Implementation Date: By January 1, 2013.

Independence at Home Demonstration Program, PPACA § 3024

This provision creates a Medicare Independence at Home Medical Practice Demonstration Program. It adds new section 1866D to the SSA.[17]- The program will test a health care delivery and payment system that uses home-based primary care from physicians, nurse practitioners, physician assistants and other home care trained providers. The program will test whether the home-based care model can improve outcomes, reduce costs, and improve patient and caregiver satisfaction. To be eligible for the demonstration, a consumer must meet the following requirements:

- enrolled in Medicare Parts A or B;
- not enrolled in Part C or PACE;
- has two high-cost chronic conditions;
- has had a non-elective hospital admission within the past 12 months;
- has received acute or subacute rehabilitation services within the past 12 months;
- has two or more functional dependencies; and
- meets other criteria Secretary may develop.

Enrollment is voluntary and should not affect access to other services. The demonstrations will begin by January 2012, for up to three years each.

Providers would need to form "legal entities," which would enter into agreements with the Secretary, and would need to meet requirements such as:

- having experience with home-based care;
- being available at all hours to patients;
- using electronic health information technology, remote monitoring and mobile diagnostic technology; and
- treating a sufficient number of patients in their home setting each year.

[17] Note that this is the same section number as the provision added by PPACA § 3023 and likely is a technical error that will need to be corrected.

Providers can subcontract with affiliated practitioners if the participation is structured in a way that is consistent with the demonstration. The Secretary will develop, and the home care entity is required to report on, quality and performance measures. The Secretary will also develop a payment methodology, including incentive payments based on performance on quality measures. The Secretary must also do a performance and cost evaluation and report to Congress, and agreements with provider groups must be terminated if a group fails to receive an incentive payment for two consecutive years or the group fails to meet quality standards in any year. The Secretary also has discretion to terminate demonstrations for other reasons the Secretary deems appropriate.

Although this provision sets out patient eligibility criteria (chronic conditions, hospitalizations, ADLs, etc.) to target consumers with high levels of need, payments are structured in a way that will have incentive effects similar to bundling and may lead to selection of only the healthiest eligible participants. This will also raise many of the other bundling concerns addresses in § 3023 under *General Concerns Regarding Bundled Care*. Of particular additional concern is whether services at home will be equally available in different geographic areas, such as poor urban or rural areas. Another specific concern will be how data is collected and recorded in the home environment, and whether this will lead to less reliable, objective or robust data.

The provision of home-based primary care services has tremendous potential to help individuals with complex clinical conditions, disabilities, and limitations in function. However, this section does not explain how this demonstration will interact with existing home and community based services programs, most notably Medicaid HCBS services, that some enrollees may already be enrolled in and more importantly which some enrollees could prospectively be enrolled in. There should be a requirement for assessments through this provision to link to home and community based services options, other demonstration programs for care coordination (although providers are prohibited from participating in this provision if they are enrolled in a § 3022 Shared Savings Program ACO), or any other health services or programs that are likely to be relevant to program participants.

This section sets out that enrollment is voluntary, and consumer choice should be respected. The form of choice and notice will be important issues for regulation.

The general description of this provision states that it is designed "to reduce expenditures and improve health outcomes."[18] The mandatory requirement to terminate a provider group that fails to receive a bonus for failing to achieve savings in two consecutive years would appear to apply even if a provider increased quality without raising costs. This could be interpreted as meaning the section places a higher priority on cost savings than quality improvement.

This section includes broad authority for the Secretary to waive specified requirements of the Social Security Act, including Title XI[19] and Title XVIII (Medicare), for the purpose of implementing the demonstration program.

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[18] *See* subsection (a)(1).

[19] Title XI is titled "General Provisions, Peer Review, and Administrative Simplification", and most importantly in this context, contains authority for demonstration projects at §1115.

Implementation Date: By January 1, 2012.

Hospital Re-admissions Reduction Program, PPACA §§ 3025, 10309

This provision reduces payments for select excess hospital re-admissions beginning October 2012.[20] The provision applies to re-admissions for measures endorsed the National Quality Forum,[21] and currently includes re-admission measures for heart attack, heart failure and pneumonia. The Secretary may add additional conditions in the future. The provision includes a complex mechanism defining how payments will be reduced. There are exceptions that apply for Medicare dependent small rural, sole community hospitals, and possibly hospitals paid under §1814(b)(3) of the Social Security Act.[22] Excess re-admissions are determined by a risk adjusted calculation of actual re-admissions compared to a specified re-admission measure rate, based on timeframes set by the Secretary according to statutory criteria. Hospitals are required to report patient data, and the Secretary must also make information about re-admissions publicly available, including on a website.

The NQF measures are risk adjusted, which should help reduce a major concern with reduction of re-admission payments: the financial incentive for hospitals to avoid necessary re-admissions, or to avoid high complexity patients for admission to begin with (because they have higher re-admission rates).

This section includes a broad provision limiting administrative and judicial review of many features of this section, including:

- base payment amounts;
- methodologies for payment adjustment; and
- re-admissions measures.

This provision also adds new § 399KK to the PHSA, to create a program within two years of enactment of PPACA for hospitals to improve their re-admission rates through the use of patient safety organizations.

Implementation Date: October 1, 2012.

Community-Based Care Transitions Program, PPACA § 3026

This provision creates a program to fund improved care transition services for high-risk Medicare beneficiaries enrolled in Parts A and B. The funding is for high re-admission rate hospitals and community-based organizations that provide transition care services. High-risk Medicare beneficiaries are identified by the Secretary of HHS based on having multiple chronic

[20] This provision amends SSA § 1886, 42 U.S.C. § 1395ww.
[21] The provision refers to the contractor under Social Security Act section 1890(a), which is currently NQF.
[22] § 1814(b)(3) hospitals operate under a state demonstration project to achieve lower than average cost rates.

conditions and re-admission and transition factors, which may include one or more of the following:

- cognitive impairment;
- depression;
- a history of multiple re-admissions; and
- other chronic disease or risk factors as determined by the Secretary.

The program is effective for five years beginning January 2011 and may be expanded further by the Secretary if it reduces spending without reducing quality. To participate, entities must submit an application to the Secretary, which includes at least one proposed intervention to improve transitions, and which is not already required in discharge planning. Some possible interventions listed by the statute include:

- care transition services not later than 24 hours prior to discharge;
- arranging timely post-discharge follow-up services;
- assistance to ensure effective interactions between patients and post-acute providers;
- provision (to patient or caregiver) of self-management support; and
- conducting medication review and management.

In selecting entities, the Secretary is to give preference to those providing services to medically underserved populations,[23] small communities and rural areas.

This provision complements PPACA § 3025 in the effort to reduce hospital re-admissions. While § 3025 reduces payments for re-admissions, § 3026 takes a more positive approach, increasing funding for activities that could reduce re-admissions. This creates the potential for funding a variety of different supports that could improve transitions. However, the entity needs only to implement one transition activity, and there are no required activities – there are only some suggested activities.

The population specifically identified by this provision, including individuals with cognitive impairment and depression, face significant barriers in the transition process. Therefore, a requirement for only one item in a non-comprehensive approach to transition assistance is likely less effective than creating an effective comprehensive baseline for transition assistance, including, for example, discharge planning follow-up, transportation and language assistance, and coordinating future care. Regulations that encourage transition services, which are more comprehensive and less one-dimensional are likely to produce better outcomes for consumers. In addition, given the population identified for assistance, there will need to be a heavy emphasis on inclusion of caregivers in the discharge plan follow-up and coordination process. At a minimum, every transition entity should have a process for ongoing identification of supports needs and referrals. For example, a consumer discharged and in danger of institutionalization after being returned to the home or community based environment should be assessed and referred for HCBS services.

[23] The term "medically underserved populations" is not defined by the statute.

It will be important for CMS to have some clear criteria for ensuring that entities receiving funding under this section are providing services that are meaningfully different than the discharge planning that is already required.[24] Furthermore, there will need to be careful analysis of when, where, and how these transitional services are provided, to ensure that they are being provided to different populations (based on race, geography, disability status, age, etc.) in an equitable fashion.

This section includes broad authority for the Secretary to waive specified requirements of the Social Security Act, including Title XI[25] and Title XVIII (Medicare), for the purpose of implementing the transitions program.

Implementation Date: January 1, 2011.

Extension of Gainsharing Demonstration, PPACA § 3027

This provision amends the Deficit Reduction Act of 2005 to extend gainsharing demonstration projects (involving hospitals and physicians) underway as of October 2008 through September 2011, and appropriates funding for 2010.

Effective Date: March 23, 2010.

Medicare Advantage Payment, PPACA § 3201; Revisions to Transitional Extra Benefits under Medicare Advantage, PPACA § 10318; Medicare Advantage Payments, Recon. Act § 1102

Recon. Act § 1102 repeals § 3201 of the PPACA in its entirety, including a clerical error in § 3201 corrected by PPACA § 10318. Recon. Act § 1102 changes the law regarding how rates for Medicare Advantage plans are determined.

Medicare Advantage plans are currently paid an average of about 114 percent of Medicare fee-for-service payment levels. This section provides for a phased-in reduction in the payment rate for Medicare Advantage plans, such that they will be paid between 95 and 115 percent of the Medicare rates, based on whether they are in a higher or lower cost area, respectively. § 1102(b). The provision also implements small payment rate increases for Medicare Advantage plans which get high quality ratings. § 1102(c). The increase is available to each plan that achieves a quality rating of four stars or more based on the most recent data available. Thus, each year, a plan will have to demonstrate this quality rating to be eligible.

Benefit protection and simplification, PPACA § 3202; Medicare Advantage Payments, Recon. Act § 1102

[24] See, eg., 42 CFR § 482.43.

[25] Title XI is titled "General Provisions, Peer Review, and Administrative Simplification", and most importantly in this context, contains authority for demonstration projects at §1115.

One problem for many beneficiaries in Medicare Advantage plans has been that these plans sometimes charge higher cost-sharing for Medicare services than the beneficiary was accustomed to paying under fee-for-service Medicare. Often beneficiaries do not realize that they will pay higher out-of-pocket costs for some services, either because they were inadequately informed of the higher costs, they received misinformation or they did not understand the information offered to them.

This section limits cost-sharing for chemotherapy administration services, renal dialysis services, skilled nursing care, and other services that the Secretary might designate to the cost-sharing levels allowed under Medicare Parts A and B. § 3202(a)(1)(B). The Secretary may allow cost-sharing for some of these "other services," even if Parts A and B generally do not require cost-sharing for the services. § 3202(a)(1)(B)(vii). These cost-sharing limits become effective for plan years starting with January 1, 2011. § 3202(a)(2).

Medicare Advantage plans have the latitude to offer additional benefits not covered under original Medicare. To attract consumers, Medicare Advantage plans have in many cases chosen to add a minimal benefit for a highly popular service (e.g. a vision benefit) instead of improving core services or reducing beneficiary cost-sharing. PPACA § 3202 requires that when a Medicare Advantage plan offers coverage or services beyond original Medicare, funds must first be applied to reducing cost-sharing, second to expanding access to key benefits such as preventive care, and third to other benefits such as vision benefits. § 3202(b)(1). These changes pertaining to the Medicare Advantage plans take effect in the 2012 plan year.

Effective date: Plan years beginning in 2012.

Application of Coding Intensity Adjustment During MA Payment Transition, PPACA § 3203; Medicare Advantage Payments, Recon. Act § 1102

Recon. Act § 1102 repeals PPACA § 3203 in its entirety.

Simplification of Annual Beneficiary Election Periods, PPACA § 3204

Note: References in § 3204 to 42 U.S.C. § 1395w-1 are likely meant to refer instead to 42 U.S.C. § 1395w-21, which matches the parallel reference in this section to § 1851 of the Social Security Act.

A substantial number of Medicare beneficiaries who enroll in Medicare Advantage plans or inadvertently enroll in plans do so because they were misled or did not understand their options. This section adds an option for beneficiaries to dis-enroll from a Medicare Advantage plan, which includes prescription drug coverage, an MA-PD plan, during the first 45 days of the calendar year, beginning in 2011. § 3204(a)(1). However, if a beneficiary dis-enrolls during this period, the beneficiary only may opt for fee-for-service Medicare, not for another MA-PD plan. The beneficiary may also choose a separate Medicare prescription drug plan, PDP, to replace the coverage lost by dis-enrolling from the MA-PD.

Many Medicare Part D beneficiaries have found it confusing to have the annual coordinated open enrollment during the winter holidays. Further, having the open enrollment period run through December 31, the day before any changes were due to take effect, also made it extremely difficult for CMS and plans to guarantee that last-minute changes would take effect as of the start of the new coverage year on January 1. This section changes the coordinated annual enrollment period, currently November 15-December 31 each year, to October 15-December 7. The open enrollment change will take effect in the fall of 2011 for the 2012 plan year. § 3204(b).

Medicare Coverage Gap Discount Program, PPACA § 3301; Closing the Medicare Prescription Drug "Donut Hole", Recon. Act § 1101

This section requires drug manufacturers to participate in the Medicare coverage gap discount program (described below). This program works in conjunction with the $250 rebate and closing of the Medicare prescription drug coverage gap described in the separate analysis of Recon. Act § 1101.

Participation in the program applies to all Medicare Part D-covered drugs dispensed after January 1, 2011. §§ 3301(a), 1101(b)(1)(A). The Secretary of HHS may grant exceptions if a drug is determined essential to the health of beneficiaries or if the Secretary determines that there are extenuating circumstances during the 2011 calendar year that warrant an exception. §§ 3301(a), 1101(b)(1)(B).

The section adds an entirely new § 1860D-14A to the Social Security Act and establishes the Medicare coverage gap discount program. The Secretary of HHS must establish the program by January 1, 2011. The Secretary must develop model agreements in consultation with drug manufacturers by 180 days after enactment (i.e. September 20, 2010). In order for the program to be able to take effect as of the beginning of 2011, the manufacturer must enter into an agreement with the Secretary by 30 days after the model agreement is developed. In subsequent years, manufacturers must enter into or renew agreements with the Secretary no later than January 30 of the previous year. The program will provide certain beneficiaries access to discounted prices on drugs at the point of sale. §§ 3301(b), 1101(b).

The discount under this program must be applied before any coverage or financial assistance applies. § 3301(b), adding Social Security Act § 1860D-14A(c)(1)(A)(v). The discounted price of 50 percent of the negotiated price from the manufacturer will only be available to people ineligible for the low-income subsidy (LIS). § 3301(b) adding Social Security Act § 1860D-14A(g)(1), (g)(4)(A). However, the entire negotiated price counts toward the beneficiary's incurred costs for purposes of meeting the beneficiary's out-of-pocket costs under the prescription drug program, an important aspect for beneficiaries who reach the "donut hole" in the program. § 3301(c)(1)(B). The program must be administered by one or more third parties with which the Secretary will contract. § 3301(b), adding Social Security Act § 1860D-14A(d)(3). The discount program and changes to the definition of best price under Medicaid become effective July 1, 2010. § 3301(c)(2), (d)(3).

Improvement in Determination of Medicare Part D Low-Income Benchmark Premium, PPACA § 3302; Medicare Advantage Payments, Recon. Act § 1102

Other sections of existing law, the PPACA, and the Recon. Act provide for higher low-income benchmark premium subsidies to Medicare Advantage plans when they meet certain quality ratings and rebates to beneficiaries' premium expenses. *See* 42 U.S.C. § 1395w-23(j); § 1102(b).

Existing law also provides in each MA-PD region for an annual low-income benchmark premium amount, which represents the amount that CMS will subsidize a MA-PD premium for a low-income subsidy-eligible person based on various factors. Beneficiaries with the subsidy have no monthly premiums if they are enrolled in a benchmark plan with a monthly premium set below the subsidy limit. If CMS sets a low benchmark, then more consumers end up in plans with premiums above the benchmark, and thus the beneficiaries are liable for partial premiums. To avoid these premium obligations, CMS reassigns these beneficiaries to other fully subsidized plans, which causes serious continuity and administrative problems.

This new section specifies that the annual benchmark premium amount is determined without regard to the beneficiary rebates and before applying the quality rating increases. § 1102(b), amending PPACA § 3302(a) and 42 U.S.C. § 1395w-114(b)(2)(B)(iii). This method of calculating the benchmark premium may encourage MA-PDs to use this funding to reduce their premiums. Therefore, by ignoring the extra MA plan income in setting the benchmark, the CMS benchmark could be higher, and fewer beneficiaries will need to go through the reassignment process.

Effective date: January 2011.

Voluntary De Minimis Policy for Subsidy Eligible Individuals Under Prescription Drug Plans and MA-PD Plans, PPACA § 3303

This section grants CMS statutory authority to continue the "de minimis" policy of allowing Low Income Subsidy (LIS) eligible individuals to remain in Part D plans that are benchmark plans in the current year and would be benchmark plans in the upcoming year except that the premiums are a de minimis amount (usually $1 to $2) over the maximum benchmark subsidy amount for the upcoming year. If a plan agrees to waive payment of the de minimis amount that the premium exceeds the subsidy, CMS will not reassign the beneficiary to another fully subsidized plan, and the beneficiary will be able to remain in the plan with a fully subsidized premium. § 3303(a). Furthermore, if plans agree to waive de minimis amounts over the maximum premium subsidy for the year, the plan can also accept auto-assignments of new enrollees who do not choose their own plans during the annual coordinated open enrollment period. § 3303(b).

This section will be very helpful to beneficiaries who are content with their existing PDP or MA-PD plans but who otherwise would be reassigned or facing a small monthly premium for prescription drug coverage if they chose to stay with the plan.

Effective date: January 1, 2011.

Special rule for Widows and Widowers Regarding Eligibility for Low-Income Assistance, PPACA § 3304

A Medicare Part D beneficiary enrolled in the LIS could potentially lose that subsidy after the death of a spouse due a change in income and family size. This section would extend the surviving spouse's eligibility for the LIS for an additional year beyond when the LIS would otherwise expire. The surviving spouse would not need to reapply, and no redetermination would be needed for the extension. § 3304(a).

This section could be very beneficial for a surviving spouse who would otherwise lose the LIS or would be put into a lesser subsidy category due to the reduced family size. However, the language of the section does not address a situation in which a couple was only eligible for the partial subsidy, and the surviving spouse's income alone may make him/her eligible for the full subsidy.

Effective date: January 1, 2011.

Improved Information for Subsidy Eligible Individuals Reassigned to Prescription Drug Plans and MA-PD Plans, PPACA § 3305

When a Medicare beneficiary's current prescription drug plan (PDP) or MA-PD will not be available the following year or will not be fully subsidized the following year, and CMS previously had assigned the beneficiary to that plan, then CMS reassigns the beneficiary to a different, fully subsidized PDP in the next year. This permits low-income, fully subsidized individuals to remain enrolled in a PDP that has no premiums for the beneficiary to pay. Under this policy, CMS randomly distributes reassigned beneficiaries among the PDPs that have premiums that will be fully subsidized. CMS does not match beneficiaries' current drug needs to the PDP formulary that best matches the beneficiary's ongoing needs. The new PDP may or may not cover all of the beneficiary's drug needs, and beneficiaries frequently do not know how they can obtain coverage for drugs that are not on the new PDP's formulary or which may be subject to utilization controls that make it harder to obtain the drugs under the formulary.

This section requires that within 30 days of a reassignment, the Secretary must provide the beneficiary with documentation of the differences in the formularies of the former and new PDPs based on the beneficiary's drug regimen. The Secretary must also inform the beneficiary how to request a coverage decision, exception, reconsideration or grievance to obtain coverage for drugs in case the beneficiary has difficulty obtaining a current medication under the new PDP.

While this section still falls short of matching a beneficiary to a PDP that might best meet his/her needs, the additional information may help a beneficiary and those who assist him/her to evaluate the new PDP's formulary and obtain coverage in the PDP for drugs that the beneficiary might otherwise have difficulty obtaining. Although the vast majority of reassignments occur at the beginning of the calendar year when the PDP landscape changes, presumably these

provisions could apply if CMS must reassign a full subsidy beneficiary due to a PDP closing down mid-year.

Effective date: No later than January 1, 2011.

Funding Outreach and Assistance for Low-Income Programs, PPACA § 3306

Current law provides for federal funding for State Health Insurance Programs (SHIP) and Area Agencies on Aging (AAA) to assist Medicare beneficiaries to understand and use their Medicare benefits effectively. MIPPA (the Medicare Improvements for Patients and Providers Act[26]) § 119 provided up to $7,5 million to states for grants to the SHIPs. This section doubles that amount of funding to $15 milion over the period of fiscal years (FY) 2010-2012. § 3306(a). This section also increases funding to the AAA by the same amount over the same period of time. § 3306(b).

The Aging and Disability Resource Centers support individuals in need of long-term care to access the various long-term care support options, including community-based care. The PPACA doubles the MIPPA funding of $5,000,000 for FY 2009 to $10 million over FY 2010-2012. § 3306(c). The PPACA appropriates $5 million to the Administration on Aging for FY 2010-2012 (the same amount as for fiscal year 2009) to inform older Americans about benefits available under state and federal programs. § 3306(d).

Each appropriation of money noted above remains available until expended. §§ 3306(a)-(d). In addition to outreach and assistance efforts, the Secretary of HHS may request that grantees use the money to conduct activities designed to prevent disease and promote wellness. § 3306(e).

Improving Formulary Requirements for Prescription Drug Plans and MA-PD Plans with Respect to Certain Categories or Classes of Drugs, PPACA § 3307

When the Medicare prescription drug program began, many beneficiaries and advocates were concerned about access to expensive, unique drugs that could not be replaced with generics or name brands available for the same disease or condition. In response, CMS developed subregulatory guidance listing six categories and classes of drugs for which prescription drug plans must cover "all or substantially all" of the drugs in those categories and classes: antiretrovirals (for HIV/AIDS), antidepressants, antipsychotics, anticonvulsants, antineoplastics (to fight cancer) and immunosuppressants (for transplant recipients). MIPPA § 176[27] statutorily required the HHS Secretary to continue the concept of requiring PDPs to cover more than the legal minimum of two drugs in each category or class for certain drugs of clinical concern. However, MIPPA did not mention the previous six classes and categories, and it did not require the Secretary to issue regulations subject to notice and comment to implement the policy.

This section improves upon the "all or substantially all" protected classes policy in several ways. The Secretary must develop written criteria for determining when certain classes

[26] P.L. 110-275.
[27] Adding 42 U.S.C. § 1395w-104(b)(3)(G).

or categories of drugs are of clinical concern. The Secretary must also establish written rules for exceptions to the policy – when a sponsor may exclude a particular drug from the PDP formulary, or may limit access to a drug through a drug management or prior authorization policy. These written criteria and exceptions must be published with a notice and comment period as federal regulations. Until such criteria are developed, the six previously noted protected classes and categories must remain protected. § 3307(a).

Effective date: Plan year 2011, beginning January 1, 2011.

Elimination of cost-sharing for certain dual eligible individuals, PPACA § 3309

Current law eliminates Medicare Part D cost-sharing for full dual eligible Part D beneficiaries who are institutionalized. 42 U.S.C. § 1395w-114(a)(1)(D)(i). This section would extend the elimination of Part D cost-sharing to full benefit dual eligibles who would be institutionalized, but are instead receiving home and community based services under a § 1115 waiver[28], a 1915(c) waiver,[29] a 1915(d) waiver,[30] or a state plan amendment to provide home and community-based services under 42 U.S.C. § 1396n(i). Cost-sharing under Medicare Part D is also eliminated for full dual eligibles who would be institutionalized but for services provided by a Medicaid managed care plan, such as an HMO or PCCM.

Effective date: On a date specified by the Secretary of HHS, but in no event earlier than January 1, 2012.

Reducing Wasteful Dispensing of Outpatient Prescription Drugs in Long-Term Care Facilities under Prescription Drug Plans and MA-PD Plans, PPACA § 3310

Under this section, the Secretary must require specific, uniform drug dispensing techniques for Medicare Part D beneficiaries in long-term care to reduce waste of prescription drugs arising from 30-day refills. The Secretary must consult with PDPs, MA-PDs, nursing facilities, residents of nursing facilities, pharmacies, the pharmacy industry and other stakeholders to develop the appropriate dispensing techniques. These techniques may include weekly, daily, or automated dosing.

Effective date: Plan years starting on or after January 1, 2012.

Improved Medicare Prescription Drug Plan and MA-PD Plan Complaint System, PPACA § 3311

The Secretary of HHS must develop a system for compiling complaints against PDPs and MA-PDs to better address major complaints and improve quality. § 3311(a). The system must be easy to use and include complaints in different formats (phone, e-mail, etc.) and those made to different entities (government agencies, contractors, etc.). The Secretary must also develop a

[28] 42 U.S.C. §1315.
[29] 42 U.S.C. § 1396n(c).
[30] 42 U.S.C. § 1396n(d).

model complaint and issue annual reports on complaints reported. § 3311(b), (c). This provision contains no date by which the Secretary must develop the new complaint compilation system.

Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans, PPACA § 3312

By January 1, 2012, each Medicare PDP and MA-PD must use a single, uniform exceptions and appeals process, and provide access to the process through a toll-free number as well as through a website. If the HHS Secretary determines that a uniform form is feasible, the Secretary may require the use of that form. This provision should be very helpful to eliminate multiple and unnecessarily complicated forms that stymie beneficiaries' rights to request exceptions and appeals to PDP coverage determinations.

Office of the Inspector General Studies and Reports, PPACA § 3313

Starting July 1, 2011, the HHS Inspector General must issue an annual report examining the degree to which PDP and MA-PD formularies include the drugs most commonly used by dual eligibles. § 3313(a). By October 1, 2011, the HHS Inspector General must also issue a report looking at the prices paid under Medicare Part D and state Medicaid programs for the 200 drugs most frequently prescribed under Part D. § 3313(b). Along with the results of this study, the Inspector General should include recommendations for administrative and legislative action. The results of these reports should be interesting to policymakers and advocates as some evidence exists showing that Part D sponsors may be paying significantly more for prescription drugs than do state Medicaid programs and others.

Including Costs Incurred by AIDS Drug Assistance Programs and Indian Health Service in Providing Prescription Drugs toward the Annual Out-of-Pocket Threshold under Part D, PPACA § 3314

Since the inception of the Part D program, Medicare beneficiaries who also depend on the AIDS Drug Assistance Program (ADAP), Indian Health Services, or various State Pharmaceutical Assistance Programs (SPAPs) have been frustrated that payments of prescription medications under those programs did not count as incurred expenses that would help the beneficiary move through the Part D donut hole. As a result, for example, many beneficiaries who are dependent on HIV/AIDS drugs became trapped in the donut hole for the balance of the calendar year.

This section changes the way that incurred costs for prescription drugs are counted, so payments made by ADAPs, Indian Health Services and SPAPs will count toward out-of-pocket expenses for a beneficiary to assist in moving the beneficiary through the donut hole. This change will not only help to alleviate costs for many beneficiaries, but it should also reduce prescription drug expenses for ADAPs, Indian Health Services, and SPAPs, as beneficiaries of these programs will be able to move through the donut hole to resume coverage under their PDPs or MA-PDs.

Effective date: January 1, 2011.

Immediate Reduction in Coverage Gap in 2010, PPACA § 3315; Closing the Medicare Prescription Drug "donut hole", Recon. Act § 1101

Recon. Act § 1101(a)(2) completely repeals § 3315 of the PPACA which closed the coverage gap. Instead, the Recon. Act implemented a new way to close the coverage gap[31] and makes a number of changes to the Medicare prescription drug program, or Part D, which affect current law, but do not amend or otherwise change sections of the PPACA. Subsections which alter provisions of the PPACA are noted in the corresponding PPACA sections analyzed in those sections. Below are the parts of this section of the Reconciliation Act that amend the law that existed prior to the PPACA.

Many Medicare beneficiaries who are not eligible for the low-income subsidy (LIS or "Extra Help") encounter the coverage gap, the so-called donut hole in the Medicare prescription drug program, at some point during the calendar year. The PPACA and the Reconciliation Act make several amendments to close that coverage gap over the next several years.

In 2010, a beneficiary who enters the Medicare prescription drug coverage gap, the so-called donut hole, will receive a flat $250 rebate. Any beneficiary who incurs costs because of reaching the initial coverage limit by the end of any calendar quarter is entitled to a check for $250 no later than the 15th day of the third month following that calendar quarter. This payment will not be made to individuals who are receiving the LIS because these beneficiaries do not encounter the coverage gap. However, it is not clear whether someone who was not enrolled in the LIS at the time she receives the payment but is later found to have been retroactively eligible for LIS would be able to keep the payment or would need to return that payment. A beneficiary may only receive one payment and only in 2010. The rebate will cause no change to the way that the Part D low-income benchmark premium will be calculated. PPACA § 3302.

Starting in 2011, coverage for the donut hole will be phased in such that by the end of 2019, the donut hole will disappear. This means that an individual who reaches the donut hole will simply continue to be obligated to pay the standard 25 percent cost-sharing that applies in the initial coverage period. Note this provision does not affect dual eligibles and other individuals who have LIS because they are not subject to the donut hole, and it also does not affect other Medicare beneficiaries whose annual drug costs do not actually reach the donut hole.

Independent Payment Advisory Board, PPACA §§ 3403, 10320

Originally titled "Independent Medicare Advisory Board" in the Senate bill, the renamed IPAB creates a powerful board to reduce Medicare spending. The Board must propose measures to reduce spending in years when spending growth will outpace target growth rates, and the Secretary must implement the proposals unless Congress enacts legislation as specified by statute (details below). Proposals must involve determinations by the CMS Chief Actuary of spending, target spending and if savings will be achieved. Proposals are prohibited from raising revenue through beneficiary cost-sharing or service reduction, and until 2019 are prohibited from reducing payment rates. The Board is required to consider factors such as quality and access in

[31] *See* Recon. Act § 1101(a).

preparing its Medicare recommendations. Starting in 2014, in years when the Board is not required to make a proposal (because spending growth does not outpace target growth rates), IPAB must submit an Advisory Report to Congress about Medicare.

The Board must submit draft copies of its proposal to MACPAC[32] and the Secretary. The statute also requires the Board to submit the proposal to the President and Congress, and (redundantly) the President is required to share any proposal with Congress. If the Board fails to make a submission, the Secretary must make a proposal and transmit it as the Board would. The proposal must be introduced into both legislative chambers and Committees, by a specified process on the first day it is submitted by the Board or President, or otherwise by any member of the chamber by the fifth day. The Board's proposal cannot be amended in ways that contradict the statutory requirements for the Board's proposal (such as producing cost savings), and only a supermajority of the Senate may override this requirement. There are further limits to debate around consideration and amendments of the proposal, and an expedited process for moving the proposal from chamber to chamber.

Notwithstanding contrary legislative or procedural action, or other limitations in the statute, the Secretary shall implement the proposal by August 15, and different pieces will be effective immediately or at the beginning of fiscal or calendar years thereafter. The Secretary may use interim final rulemaking. There are exceptions whereby the Secretary is not required to implement a proposal if: Congress enacts legislation to override the proposal; or if there was a proposal required in the previous year and growth in Medicare spending is below national health spending. The Secretary may implement pieces of any proposal pursuant to other powers, if applicable. The Board may be dissolved only by a joint resolution approved by a supermajority vote of both the House and Senate.

The Board itself is composed of 15 members including a chairperson, all appointed by the President with Senatorial consent, along with several non-voting members selected from agency staff. There are general requirements for Board membership, along with the specific requirement that the Board include consumers and not have a majority of medical providers. There are provisions requiring ethical disclosure, conflicts of interest and lobbying cool-off periods. Board membership is six years, limited to two full terms. Board voting is by majority. The Board can conduct hearings,[33] provide advice to the Secretary, and obtain official data from any department or agency of the United States if needed. Board members are paid and reimbursed for travel, and the Board may hire some staff.

A 10-member Consumer Advisory Council is established to advise the Board about consumer impacts of proposed policies. The Council is totally separate from the IPAB, and has a strictly advisory capacity. The Council members are appointed by the Comptroller General, who selects one consumer from each of 10 regions. The Council shall meet in open public meetings at least twice a year, subject to the call of the Board. The Federal Advisory Committee Act,

[32] The Medicaid and CHIP Payment and Access Commission, or "MACPAC", was established by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) to advise Congress on a wide range of Medicaid and CHIP topics.
[33] It is not specific whether the Board has subpoena powers.

except § 14,[34] shall apply to the Council. For purposes of this provision, the term "Medicare beneficiary" is defined as eligible or enrolled for Parts A or B only. The Comptroller General must periodically study and report on the effect of changes to Medicare by recommendation of the IPAB upon access, affordability and quality.

By July 2014 the Board must begin issuing non-binding annual public reports on system-wide health care costs (not only Medicare, and presumably including Medicaid), access, use and quality information, which allows for comparison by service and provider types, geography, and payer. By 2015 the Board must issue every two years non-binding public recommendations to slow national health care spending for non-federal health care programs.

This Board is specifically created with the purpose of reducing the growth in Medicare spending. However, in the Reconciliation law, IPAB has an added a function to also make general reports and recommendations concerning system-wide spending, and the reports (but not recommendations) will include Medicaid. Given that the purpose of this body is to cut costs, and the protections against reducing services or adding cost-sharing are applied to Medicare, advocates may want to ensure that reports do not target reductions in the Medicaid program.

The prime target of the program savings appears to be Medicare providers and contractors through rate-setting. This is evidenced by the provision's: prohibition on raising cost-sharing or reducing savings for patients; allowance for rate adjustments immediately for Parts C and D, and by 2019 for Parts A and B; and specific preclusion of more than half of the Board members being providers. The IPAB is also likely to make non rate setting suggestions regarding cost-saving ideas like bundling and ACOs. See analysis in § 3023 on *General Concerns Regarding Bundled Care.*

Although consumers are not directly the prime target, the IPAB will wield significant power with its purpose to cut costs, and its actions are likely to impact consumers in more negative ways than positive ways. Any authority to reduce Medicare rates could drastically affect access to Medicare providers, particularly considering that there are projected to be 16 million new individuals covered by private payors seeking medical providers after reform. Because the most foreseeable results of this Board's actions may on balance be negative for consumers, regulations or sub-regulatory policy should carefully circumscribe and condition the substantive and procedural power of this Board to reduce the threat to consumers.

The composition of the 15-member Board is difficult to predict. Although there is a requirement to include consumer representation, there is no requirement as to quantity of consumers or qualifications to be a consumer representative. Regulation or sub-regulatory policy could clearly state a proportional requirement, such as one-third consumers, and could identify who could be properly classified as a consumer (or consumer representatives to the extent they are allowed to occupy consumer positions).

The creation of a Consumer Advisory Council is an important development for consumers and should be bolstered in the regulatory process. It is important that this Council

[34] Section 14 relates to Termination of advisory committees; renewal; continuation, *See* 5 U.S.C. § 14,

should not take the place of consumer positions on the Board or reduce the number of places on the Board; consumers need seats at the Board table, not an advisory capacity that would be meaningless with a disinterested Board.

This provision has important language requiring Board representatives generally to disclose conflicts of interests. Regulation could present an opportunity to further enhance this protection, adding details such as requiring recusal from specific votes where conflicts are relevant or providing regulation to clarify the explicit allowance of gifts.[35]

This section includes a broad provision limiting administrative and judicial review of the Secretary's implementation of the recommendations in an IPAB proposal.

Effective Dates: 2012 (funding); by April 30, 2013 (CMS Actuary assessment); January 15, 2014 (Board action).

Establishing Community Health Teams to Support the Patient-Centered Medical Home, PPACA §§ 3502, 10321

This provision requires the Secretary of HHS to implement a grants program for or contract with entities to establish community-based health teams to support primary care, including obstetric and gynecological care, or make capitated payments to the providers. To be eligible, entities must ensure they create health teams that include a full range of providers (as required by the Secretary) and must submit a plan for prevention and care management, along with other requirements. Health teams established by the entities must deliver patient-centered care, meet numerous care requirements,[36] and work and collaborate with a range of providers and community health stakeholders. Entities must make reports to the Secretary per request.

This provision dedicates funding to expanding access to patient-centered care management through a team approach. To do this most effectively will require careful review of which initiatives are truly expanding access and creating a team around the patient. It will be essential to develop a set of measures that truly capture which consumers are participating, what their experiences are like, and what their outcomes are.

There is great potential for actually funding care coordination through a wide range of providers, including physicians, nurses, social workers and health educators. It will be important for regulations to address the way this care coordination interacts with other demonstration projects in the health reform law and other public programs generally. For example, these care coordinators need to know about Medicare home-based care (see § 3024) or Medicaid HCBS programs.

Effective Date: March 23, 2010.

[35] *See* subsection (i)(5).

[36] These include providing access to specialty care, preventive care, and inpatient services, promoting monitoring of health outcomes and collecting and recording data, among many others.

TITLE IV—PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH

School-Based Health Centers, PPACA § 4101

This section authorizes the HHS Secretary to award grants to support the operation of school-based health centers. To be eligible, an entity must be a school-based center and must submit an application stating that under the grant it will not use awarded funds for any service not allowed by federal, state or local law. In awarding grants, the Secretary can give preference to schools serving a large population of children eligible for Medicaid or CHIP. The funds can only be used for expenditures for facilities or equipment, not costs associated with personnel or providing health services. Fifty million dollars will be appropriated each year for the fiscal years 2010 through 2013. § 4101(a).

The provision adds PHSA § 399Z-1, which defines "physical services" and "mental health services" under comprehensive primary health services, "medically underserved children and adolescents," and "school-based health center." It also establishes criteria for determining specific shortages of personal health services for medically underserved children and adolescents. A school-based health center is defined as "a health clinic that . . . provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals," but does not perform abortion services. § 4101(b), amending 42 U.S.C. § 280h et seq.

The HHS Secretary must also award grants for the cost of operating school-based health centers. Unlike the grants discussed above, funds from these grants can be used for equipment, training, management and operation of health center programs, and payment of salaries, but not for abortions. To be eligible, an entity must be a school-based health center and submit an application evidencing the local need for services and assuring that the center will:

- provide services to children for whom parental consent has been obtained;
- make reasonable efforts to establish and maintain collaborative relationships with other health care providers;
- provide on-site access during the academic day and 24-hour back-up coverage through an on-call system; and
- be integrated into the school environment and coordinate health services with school personnel.

The Secretary may give preference to applicants who demonstrate an ability to serve communities that have:

- evidenced barriers to primary care;
- high per capita numbers of underinsured, uninsured and those enrolled in public health services programs; and

- populations of children and adolescents with historically demonstrated difficulty accessing health services.

School-based health centers provide a tremendous opportunity for children, including those who are at-risk or otherwise lack meaningful access to adequate health care services, to obtain medically necessary care. However, the parts of this section that prohibit the provision of services to which a parent has not consented prevent children from having meaningful access. The refusal of school-based health centers to perform abortions that may be medically necessary undermines quality care for young women in that environment, as does the severe restriction that services provided at the center be consented to by a parent. Moreover, evidence that adolescents may avoid seeking necessary and appropriate medical care that requires knowledge and consent by their parents is well-documented in the public health literature and demonstrates the counterproductiveness of this provision.

Effective date: March 23, 2010.

Oral Healthcare Prevention Activities, PPACA § 4102

This provision establishes a five-year national, public education campaign that focuses on oral health prevention and education, including prevention of oral disease such as early childhood and other caries, periodontal disease and oral cancer. The campaign should be targeted to specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and Indians and Native Alaskans. The campaign will utilize science-based strategies to convey oral health prevention messages. The campaign is to be implemented within two years of enactment of PPACA. §§ 4102(a), (b) (amending 42 U.S.C. § 241 et seq.).

The provision also directs the HHS Secretary, through the Director of Centers for Disease Control and Prevention, to award demonstration grants on the effectiveness of research-based dental caries disease management activities. It authorizes appropriation of funds for school-based sealant programs and directs the Secretary to:

- update and improve the Pregnancy Risk Assessment Monitoring System (PRAMS), which provides state-specific data for planning and evaluating health programs to improve the health of mothers and infants by reducing adverse outcomes;
- develop oral health components that include tooth-level surveillance for inclusion in the National Health and Nutrition Examination Survey (NHANES); and
- ensure that verification of dental utilization, expenditure and coverage findings are included in the Medical Expenditures Panel Survey.

Finally, the provision authorizes appropriation of funds to increase participation in the National Oral Health Surveillance System (NOHS) and requires the Secretary to ensure that NOHS includes the measurement of early childhood caries. §§ 4102(c) (amending 42 U.S.C. § 247b-14), (d).

Effective date: March 23, 2010.

Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan, §§ 4103, 10402(b)

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) improved and eliminated cost-sharing for the Medicare benefit for an initial preventive physical examination during the first 12 months that a beneficiary has Part B coverage, but made no provision for ongoing wellness visits or care planning. Aside from the MIPPA "Welcome to Medicare" visit, Medicare beneficiaries traditionally have not had access to preventive services. This section establishes an annual wellness visit for preventive care, along with a personalized assessment of risk behaviors and factors with referrals to resources to address those health behaviors or factors in subsequent years. §§ 4103, 10402(b). The PPACA prohibits cost-sharing for this service. § 4103(c)(3). There are some limits regarding the frequency of these visits, as this is designed to be an annual process. The annual wellness visits may be furnished through interactive telephonic or web-based programs. § 4103(a) (adding subsections 42 U.S.C. §§ 1395x(hhh)(4)(A)(ii)(I), (hhh)(4)(B)).

Effective date: January 1, 2011.

Improving Access to Preventive Services for Eligible Adults in Medicaid, PPACA § 4106

Currently, Medicaid law allows states to cover "other diagnostic, screening, preventive and rehabilitative services…recommended by a physician or other licensed practitioner of the healing arts…." 42 U.S.C. § 1396d(a)(13). The PPACA expands the definition of preventive services that a state may cover as optional services under Medicaid. This definition now includes services that are assigned an A or B by the United States Preventive Services Task Force. The preventive services also now clearly include recommended vaccinations for adults. *Id*. If a state provides these services and prohibits cost-sharing for these services and vaccines, the state is eligible to receive an extra one percent in FMAP to help cover the additional costs for these services and vaccines.

Effective date: January 1, 2013.

Coverage of Comprehensive Tobacco Cessation Services for Pregnant Women, PPACA § 4107

The PPACA expands the services covered by Medicaid by requiring coverage of products, drugs and therapies to help pregnant women stop smoking. PPACA § 4107 (amending 42 U.S.C. § 1396d(a)(4)). The covered services include diagnostic, therapy and counseling services, and prescription and non-prescription drugs and products approved by the Food and Drug Administration for smoking cessation. The specific services are those recommended in the Public Health Service guidelines "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline," its subsequent updates and other such services designated by the Secretary. PPACA § 4107(a).

Smoking cessation products for pregnant women can no longer be excluded from optional state drug coverage. PPACA § 4107(b) (amending 42 U.S.C. 1396r-8(d)(2)(F)). Smoking cessation treatment and products are also added to the services for pregnant women that are exempt from cost-sharing. PPACA § 4107(c)(1) (amending 42 U.S.C. § 1396o(a)(2)(B) and (b)(2)(b)).

Effective date: October 1, 2010.

Incentives for Prevention of Chronic Diseases in Medicaid, PPACA § 4108

This section appropriates $100 million to HHS to make grants to states for innovative programs that will provide incentives to Medicaid beneficiaries to improve their health and avoid certain chronic conditions. § 4108(a)(1), (f). The initiatives should "test approaches that may encourage behavior modification and determine scalable solutions." § 4108(a)(1)(B), (a)(3)(A). Participation in the initiatives is open to beneficiaries eligible for Medicaid as well as those eligible under Medicaid waivers. § 4108(g)(1). Funded initiatives will address:

- cessation of tobacco product use;
- control or reduction in weight;
- lowering of cholesterol;
- lowering blood pressure; or
- avoiding the onset or better managing of diabetes. § 4108(a)(3)(A).

An initiative also may deal with a combination of these conditions or co-morbidities, such as depression. § 4108(a)(3)(B).

States have the flexibility to contract with providers, community-based organizations, faith-based groups, Indian tribes and other organizations to implement the initiatives. § 4108(a)(3)(D). The HHS Secretary has the authority to waive statewideness for these initiatives. § 4108(a)(3)(C). Any incentives offered to a beneficiary under an initiative cannot be taken into account when determining eligibility or level or amount of benefits under Medicaid or any other program that receives federal funding. § 4108(e). This last point is significant in two ways. First, the value of the incentive cannot be used in determining an individual's or family's income eligibility for a public benefit. Secondly, in recent years some states have denied certain Medicaid services to beneficiaries who did not "comply" with less than entirely voluntary "agreements" to modify behaviors. While states cannot withhold Medicaid services or eligibility as a "hammer" to force beneficiaries to comply, this section is not dispositive about whether a state could require a beneficiary or group of beneficiaries to participate in an initiative. Nevertheless, requiring a beneficiary to participate would seem counter to the clear intent of the law to create "incentives."

The HHS Secretary must do outreach and education to states to raise awareness of the grants, and states that receive grants must engage in outreach and education to providers and beneficiaries about the funded initiatives. § 4108(b). Funded initiatives must include tracking of beneficiaries' progress, standards and health status targets, and evaluation of effectiveness –

including an independent analysis by an agency or organization with which HHS contracts to evaluate the initiatives. § 4108(c), (d)(1). States must report on processes developed, lessons learned, and preventive services. § 4108(c). The Secretary must submit a report to Congress by January 1, 2014 on the initial progress of the grants and whether to continue funding or expanding the program beyond January 1, 2016. § 4108(d)(3).

The HHS Secretary may begin awarding grants by January 1, 2011, or sooner if program criteria are developed before that date. § 4108(a)(2)(A). Initiatives funded under the program must last at least three years and must be carried out before January 1, 2016. § 4108(a)(2)(B).

Community Transformation Grants, PPACA §§ 4201, 10403

HHS, through the Center for Disease Control (CDC), is required to issue competitive community grants to state and local governments and community-based organizations to implement and evaluate community preventive programs to promote healthy living and reduce health disparities.

Entities that are eligible to receive a grant include: a state and local government agency, national network of community-based organizations, state or local non-profit, or an Indian tribe. At least 20 percent of the grants must go to grantees serving rural or frontier areas.

Section 4201 outlines activities that may be included in the grant but notes it is not an exclusive list. Those activities include:

- creating healthier school environments;
- developing and promoting programs that advance nutritional, social and emotional wellness, or a chronic disease priority area;
- prioritizing strategies that will help reduce health disparities, including social, economic and geographic determinants of health; and
- assisting special populations including persons with disabilities.

There must be an evaluation component of the grant that measures specific outcome measures such as changes in weight, proper nutrition or tobacco use. That evaluation must be reported back to CDC. CDC has an obligation to bring the grantees together and to provide training in certain areas.

These grants provide an opportunity to support local and community efforts to reduce chronic illness and disability, and assist populations that are particularly disadvantaged, as well as address ongoing health disparities.

Effective date: March 23, 2010.

Healthy Aging, Living Well; Evaluation of Community-Based Prevention and Wellness Programs for Medicare Beneficiaries, PPACA § 4202

This provision has two parts. Under "Healthy Aging, Living Well," the HHS Secretary is directed to award grants to state or local health departments to conduct five-year pilot programs to improve the health of 55-to-64-year-olds. Activities should be in conjunction with Centers for Disease Control and Prevention and the Administration on Aging and include interventions, screenings, and referral/treatment. Individuals who are uninsured should be referred to an established community partner for public insurance coverage screening. Evaluations are required by participants and by the Secretary.

Under the second part of this provision, the Secretary must evaluate community-based prevention and wellness programs for Medicare beneficiaries. A separate evaluation must by lead by the Administrator of CMS and the Assistant Secretary of Aging. The HHS Secretary must submit a report to Congress by September 30, 2013, based on the Secretary's findings, and reviews of evidence and the Administrator's evaluation.

For this section, "Medicare beneficiary" is defined as entitled to Part A (whether enrolled or not) and enrolled in Part B.

This provision is an attempt to reduce future Medicare costs by improving the ongoing health status and maintenance of the 55-to-64 year population as it approaches Medicare eligibility. Activities to improve health and prevention will need to be carefully selected to ensure that they address the appropriate health needs for appropriate communities. Some areas may have particular disease patterns (for example, high incidence of diabetes), special factors that affect wellness (for example, the need for language services), or other specific issues that influence which programs will be most useful. Regulations will need to set a process to correctly identify optimal strategies in different communities.

In addition, it will be essential to evaluate where grants are being conducted to ensure that grants target different populations equitably, and particularly focus on populations that have the poorest health status and are in the most need of improved access to preventive services.

Effective Date: March 23, 2010.

Removing Barriers and Improving Access to Wellness for Individuals with Disabilities, PPACA § 4203

This section amends Title V of the Rehabilitation Act of 1973. Within 24 months after enactment of the PPACA, the Architectural and Transportation Barriers Compliance Board (ATBCB), in consultation with the Commissioner of the FDA, is required to promulgate regulations establishing minimum physical accessibility requirements for medical diagnostic equipment used in hospitals, clinics, physician's offices, emergency departments and other medical settings. § 4203(a). Equipment covered includes examination tables and chairs, weight scales, mammography equipment, X-ray machines and other radiological equipment. § 4203(b). ATCBA and the FDA must periodically review and amend these standards and determine whether the program should be expanded. § 4203(c).

This provision addresses a significant gap in current law, as access to this equipment has not previously been regulated by federal laws such as the Rehabilitation or Americans with Disabilities Acts. The regulations will affect both publicly funded and private health care providers.

Effective date: March 23, 2010.

Immunizations, PPACA § 4204

This section gives the HHS Secretary authority to negotiate and contract with vaccine manufacturers for the purchase of vaccines for adults who are Medicare beneficiaries over the age of 65. States are also permitted to purchase additional quantities of adult vaccines at Secretary-negotiated rates. § 4204(a) (amending 42 U.S.C. § 247b).

By awarding grants to states, the section also establishes a demonstration program to improve immunization coverage to children, adolescents and adults using evidence-based, population-based interventions for high-risk populations. Funds will be used to implement interventions recommended by the Task Force on Community Preventive Services, including:

- providing immunization reminders for target populations;
- educating targeted populations and health care providers;
- reducing out-of-pocket costs for families; and
- providing for home visits.

In addition to evaluation by states and a report to Congress, the GAO shall conduct a study no later than June 1, 2011, on the ability of Medicare beneficiaries to access routinely recommended vaccines. § 4204(b) (amending 42 U.S.C. § 247(b), (e).

Effective date: March 23, 2010.

Reasonable Break Time for Nursing Mothers, PPACA § 4207

Section 4207 provides accommodations for nursing mothers in workplace settings, by requiring that employers:

- provide a reasonable break time for the employee to express breast milk for a nursing child when the need arises, without compensation if the break occurs during work time; and
- provide a private area (other than a bathroom) for the employee to express breast milk that is free from intrusion.

Employers with fewer than 50 employees are exempt from these provisions if they would impose an undue hardship. Further, state laws governing this issue that provide greater protections are not preempted by § 4207.

Advocates and health providers should support initiatives based on this provision because they provide an opportunity to help improve the health of infants, particularly those who are from communities experiencing a significant level of infant health disparities.

Understanding Health Disparities: Data Collection and Analysis, PPACA § 4302

This provision addresses a number of deficiencies in federal data collection needed to identify health disparities. First, within two years of the date of enactment, HHS must collect and report data in any federally conducted or supported health care or public health program, activity or survey (including Current Population Surveys and American Community Surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census). Second, HHS must also require that any reporting requirement imposed for quality measurement under any ongoing or federally conducted or supported health care or public health program, activity, or survey includes requirements for the collection of data on individuals receiving health care items or services.

Third, any race and ethnicity data must also be collected regarding underserved rural and frontier populations. HHS must consult with the Director of the Office of Personnel Management, the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the Bureau of the Census, the Commissioner of Social Security and the head of other appropriate federal agencies in carrying out this section.

The data that must be collected includes, to the extent practicable:

- data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants;
- data at the smallest geographic level such as state, local or institutional levels if such data can be aggregated;
- sufficient data to generate statistically reliable estimates by racial, ethnic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and
- any other demographic data as deemed appropriate by the Secretary regarding health disparities.

Fourth, for collecting race and ethnicity data, HHS must use the Office of Management and Budget standards. It must also develop new standards for collecting sex, primary language and disability status. These standards must require, at a minimum, self-reported data by the applicant, recipient, or participant and collection of data from a parent or legal guardian if the applicant, recipient, or participant is a minor or legally incapacitated. HHS must survey health care providers and establish other procedures to assess access to care and treatment for individuals with disabilities and to identify:

- locations where individuals with disabilities access primary, acute (including intensive) and long-term care;

- the number of providers with accessible facilities and equipment to meet the needs of the individuals with disabilities, including medical diagnostic equipment that meets the minimum technical criteria set forth in § 510 of the Rehabilitation Act of 1973; and
- the number of employees of health care providers trained in disability awareness and patient care of individuals with disabilities.

Fifth, HHS, through the National Coordinator for Health Information Technology, is also tasked with developing national standards for the management of data collected, and interoperability and security systems for data management. HHS must analyze this data to detect and monitor trends in health disparities at the federal and state levels. HHS must make its analysis available to:

- the Office of Minority Health;
- the National Center on Minority Health and Health Disparities;
- the Agency for Healthcare Research and Quality;
- the Centers for Disease Control and Prevention;
- the Centers for Medicare & Medicaid Services;
- the Indian Health Service and epidemiology centers funded under the Indian Health Care Improvement Act;
- the Office of Rural Health;
- other agencies within the Department of Health and Human Services; and
- other entities as determined appropriate by the Secretary.

Sixth, in addition to sharing the analysis internally within HHS, HHS must report data and analyses on its website and through any other reporting or dissemination mechanisms determined appropriate by the Secretary. HHS may make this data available for additional research, analyses and dissemination to other federal agencies, non-governmental entities, and the public, in accordance with any federal agency's data user agreements. But the data may not be used in any way that would adversely affect any individual. Further, the data must be subject to privacy protections at least as strong as applied to HIPAA protected data. The data must be protected from all inappropriate internal use by any entity that collects, stores or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary. HHS also must ensure all appropriate information security safeguards are used in the collection, analysis and sharing of this data. HHS will establish procedures for sharing this data with relevant state and federal agencies including those listed above.

The provision allocates such sums as may be necessary for each of fiscal years 2010 through 2014. But it also states that data may not be collected pursuant to this section unless funds are directly appropriated for such purpose. This is unfortunate because this may significantly limit the collection of this data, much of which could be undertaken under current authority without needing financial appropriations.

The provision also amends the Medicaid and CHIP statutes to comply with this section. In Medicaid, states often collect race and ethnicity data, but CMS has not required this data to be collected using either OMB any other uniform standards. The result is a patchwork of race and

ethnicity categories used by different states, and an inability to compare race and ethnicity data across states. Thus, states will be required to use the OMB standards for collecting race and ethnicity. For CHIP, the provision requires compliance with this section and also specifically notes the need to collect language data of enrollees, and for enrollees who are under 19, the primary language of the enrollee as well as the enrollee's parent(s)/guardian(s). However, because of the funding limitation above, it is unclear whether Medicaid and CHIP could require these changes even if funding is not needed.

For Medicaid and CHIP, a new section is added to the Social Security Act, § 1946. This section requires HHS to evaluate approaches for collecting data under Medicaid and CHIP along with existing quality reporting requirements. The goal is to allow ongoing, accurate, and timely collection and evaluation of data on disparities in health care services and performance on the basis of race, ethnicity, sex, primary language and disability status. HHS must take into account objectives including:

- protecting patient privacy;
- minimizing the administrative burdens of data collection and reporting on states, providers and health plans participating in Medicaid/CHIP; and
- improving program data under Medicaid and CHIP on race, ethnicity, sex, primary language and disability status.

Not later than 18 months after enactment, the Secretary must submit a report to Congress on this evaluation and identify approaches (including defining methodologies) for identifying, collecting and evaluating data on health care disparities on this data for the programs under Medicaid and CHIP. The report must also include recommendations on the most effective strategies and approaches to reporting HEDIS quality measures and other nationally recognized quality performance measures, as appropriate. Within 24 months of enactment, HHS must implement the approaches identified in this report for the ongoing, accurate, and timely collection and evaluation of this data on health care disparities. The Secretary must submit a report to Congress that includes recommendations for improving the identification of health care disparities for beneficiaries under Medicaid/CHIP based on analyses of the data every four years, beginning four years after enactment.

TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY

Patient-Centered Outcomes Research, PPACA §6301, 10602

This provision amends Title XI of the Social Security Act, adding a new part[37] titled "Comparative Clinical Effectiveness Research," which is research to compare the effectiveness, risks and benefits of two different treatments. The provision establishes a nonprofit corporation, the Patient-Centered Outcomes Research Institute, and a related fund for it. The Institute will conduct research to inform treatment effectiveness. The Institute will identify research priorities and an agenda, and carry out research and enter into contracts for research and research management by processes laid out in the statute. The Institute will have access to national and state program data, subject to privacy protections. The Institute may appoint advisory panels o assist in identifying research priorities and establishing the research project agenda and for other purposes. It must create advisory panels to advise it in carrying out randomized clinical trials or to assist in the design of research on rare diseases. Further, it must incorporate peer-review, and must provide special support to consumers to promote their advisory role. A 15-member methodology committee, selected by the Comptroller General, will develop the science and methods of clinical effectiveness comparison. The Methodology Committee must submit reports to the Institute's Board of Governors.[38] Within 90 days of developing research conclusions, the Institute must share the results publicly, and the Institute must make an annual report available to Congress, the President, and the public. The Institute will adopt measures on a majority vote basis.

The Institute will have a Board of Governors to carry out its duties. The Board is formed by 36 individuals, including various agency members designated by the statute, Comptroller General appointments, providers, three consumer representatives and others. Terms are for six years, with a maximum of two consecutive terms. The Board members are paid, will have staff and must hold meetings publicly. The Institute will be subject to independent financial audit and a review and report by the Comptroller General. The Institute must ensure there are public comment periods for decisions, forums to increase public awareness, public website availability of information, and disclosure of conflicts of interest.

The provision[39] also amends the PHSA to require the Office of Communication and Knowledge Transfer to broadly disseminate research findings from the Institute, including "a description of considerations for specific subpopulations." The Office must have a process to receive feedback from stakeholders, including consumers. The Office will also establish a grant program to provide training for clinical effectiveness research. The Secretary must implement a data network to allow collection and analysis of research.

Under this provision,[40] the Secretary can only use comparative effectiveness research to make coverage determinations if there is a transparent process that includes consumer comment

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[37] Social Security Act §1181.
[38] The Institute's Board of Governors is also created by this provision, at Social Security Act §1181(f).
[39] At PPACA §6301(b).
[40] At PPACA §6301(c).

and considers the effect on subpopulations. The provision specifically proscribes using evidence in a way that values young life more than old life, relies solely on clinical effectiveness data in coverage determinations, or trumps how an individual values tradeoffs between quantity and quality of life. The Institute is also proscribed from using methods that quantify the value of life in a way that diminishes the value of a disabled life. The disparate treatment of disabled individuals in the health care system has been a long-standing failure in health care equity. For example, disability advocates have long fought to prevent decisions to reduce the scope and amount of care provided to disabled patients solely because patient has a disability.

The provision[41] also creates and finances a trust fund for the research in this provision. It also creates a new fee on accident and health insurances to partially fund the research. The Institute itself is tax-exempt.

Comparative clinical effectiveness research, the ultimate product of this provision, has been caught in a political battle between interests intending to focus the health system on evidence-based treatment and interests focused on maximizing personal autonomy in health care spending. As a result, this provision is the result of a political compromise with uncertain legal applicability. On the one hand, this provision establishes an entity and funding to conduct clinical effectiveness research to "assist patients, clinicians, purchasers, and policy-makers in making informed decisions." On the other hand, the provision tightly circumscribes the use of any results of clinical effectiveness research or the development of quantifications such as "dollars-per-quality adjusted like year." It is likely that even the clearest research results could not be used to shape coverage or reimbursement determinations without an exhaustive process (including, for example, public comment) that would be subject to numerous points of legal challenge (such as the prohibition of using the research to preclude an individual's personal valuation of the tradeoffs between extending life and the risk of disability).

To the extent this provision advances comparative effectiveness research, it will be important that consumer advocates shape the driving forces behind the research. This research could be used exclusively as a cost-cutting vehicle, which could erode consumer access to services. However, this research also has tremendous potential to help consumers – for example, highly invasive and profitable procedures that are favored by the medical industry but are proven clinically ineffective could be avoided.

Effective Date: March 23, 2010.

Federal Coordinating Council for Comparative Effectiveness Research – PPACA §6302

This provision terminates the Federal Coordinating Council for Comparative Effectiveness Research created by ARRA (2009). Note that the Council is effectively replaced by the Institute created under PPACA §6301.

Effective Date: March 23, 2010.

[41] At PPACA §6301(d) and §6301(e).

Provider Screening and Other Enrollment Requirements under Medicare, Medicaid, and CHIP, PPACA §§ 6401, 10603, Recon. § 1304

This section amends § 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) and requires states to comply with the following provider and supplier screening, oversight and reporting requirements described below:

- new procedures for screening Medicaid and CHIP providers set up by the Secretary of HHS that include a licensure check and may also include a criminal background check, fingerprinting, unscheduled site visits and database checks, and other screening;
- provisional period of enhanced oversight for new providers, such as pre-payment review and payment caps;
- increased disclosure requirements for providers of any current or previous affiliations;
- temporary moratorium on enrollment of new providers to prevent or combat fraud, waste or abuse;
- compliance programs for providers and suppliers of medical and other services;
- state compliance of reporting adverse provider actions including criminal and civil convictions, sanctions, negative licensure actions, and other adverse provider action to the Secretary, through CMS;
- enrollment and national provider identifier of ordering or referring providers; and
- existing or enhanced state oversight of provider and supplier activity beyond that of the Secretary.

This section also provides that the CMS Administrator will report Medicare and CHIP terminated providers and suppliers to each state Medicaid agency. § 6401(b)(2).

Effective date: March 23, 2010.

Enhanced Medicare and Medicaid Program Integrity Provision, PPACA § 6402, Recon. § 1304, 1303

This section adds a new § 1128J title XI of the Social Security Act (42 U.S.C. 1302 et seq.). The provision addresses development of an integrated data repository and penalties for beneficiary fraud.

The CMS Integrated Data Repository (IDR)

The IDR will match Medicaid claims and payment data and Medicare, CHIP, Veterans Administration, Department of Defense, Social Security Administration, and Indian Health Service data in any appropriate system of records (based on the Privacy Act) to identify potential fraud, waste, and abuse in Medicaid and Medicare. The HHS Office of Inspector General (OIG) has access to any supporting documentation for Medicaid or Medicare claims or payments, including: medical records for a individual prescribed a Medicare Part B-covered item or service; a Medicare Part D covered drug paid for by a MA-PD plan under Medicare Part C or a Medicare Part D drug plan; and any records necessary for evaluation of the economy, efficiency and effectiveness of Medicare or Medicaid. § 6402(a).

Penalties for Beneficiary Fraud

The Secretary will impose administrative penalties on Medicare, Medicaid, and CHIP beneficiaries for knowing participation in or conspiracy to commit federal health care fraud. § 6402(a).

Other topics addressed in this section include:

- reporting and repayment of overpayments;
- requirement for Medicare and Medicaid National Provider Identifier on all payment claim and applications to enroll in Medicaid or Medicare. The Secretary must promulgate a regulation that requires, not later than January 1, 2011, the inclusion of this information;
- withholding of federal matching payments for states that fail to report enrollee encounter data;
- making false statements or misrepresentation of material facts on provider agreement, bid, or contract to participate or enroll;
- testimonial subpoena authority in exclusion-only cases;
- kickbacks;
- surety bond requirements for DME, home health agencies and other providers;
- suspension of Medicaid payments pending investigation of credible allegations of fraud;
- increased funding to fight fraud and abuse;
- Medicaid Integrity Program; and
- expanded application of hardship waivers for exclusions.

Effective date: March 23, 2010.

Additional Medicaid Program Integrity Provisions, PPACA § 6501 – 6508

The following issues are covered in this section.

- termination of provider participation under Medicaid if terminated under Medicare or other state plan (§ 6501);
- Medicaid exclusion from participation relating to certain ownership, control, and management affiliations (§ 6502);
- requirement for registration under Medicaid for billing agents, clearinghouses, or other alternate payees that submits claims on behalf of a health care provider (§ 6503);
- requirement that states and managed care organizations report an expanded set of data elements under Medicaid Management Information System (MMIS) to detect fraud and abuse (effective date: January 1, 2010, § 6504);
- prohibition on payments for items or services provided under the state plan, or under a waiver to financial institutions or entities located outside of the United States (§ 6505);

- extension of collection period of fraud overpayments from 60 days to one year (the effective date : March 23, 2010 and applies to overpayments discovered on or after that date, § 6506); and
- mandatory state use of national correct coding initiative methodologies (effective date: for claims filed on or after October 1, 2010, § 6507).

Effective date: Unless otherwise noted, the provisions are effective on January 1, 2011. A delay of one regular session of the state legislature after March 23, 2010, is allowed if state legislation is necessary for compliance.

TITLE VIII—CLASS ACT

The Community Living Assistance Services and Supports (CLASS) Act Amendments to the Public Health Services Act, PPACA §§ 8001-8002

Purpose and Definitions

The purpose of the CLASS Act is to establish a national, voluntary insurance program to cover the costs of purchasing community living assistance services and supports to:

- provide individuals with functional limitations with the tools that will enable them to maintain personal and financial independence and live in the community;
- establish an infrastructure to help address the national community service and support needs;
- alleviate the burden on family caregivers; and
- address institutional bias. § 8002(a), adding PHSA § 3201.

An eligible individual is defined as an active enrollee in the program who:

- has paid premiums for enrollment in the program for at least 60 months;
- has earned, during at least three calendar years occurring during those 60 months, at least the amount of income that would credit that individual for a quarter of coverage under the Federal Old Age, Survivors, and Disability Insurance Act (42 U.S.C. § 413(d));[42]
- has paid premiums for at least 24 consecutive months of the period between enrollment in the program and the date an individual is determined to qualify; and
- is certified to have a functional limitation that is expected to last for a continuous period of more than 90 days. PHSA § 3202(6).

The Act specifies that the terms "hospital," "nursing facility," "intermediate care facility for the mentally retarded" and "institute for mental diseases" have the meanings given for the purpose of Medicaid. PHSA § 3020(7).

Class Independent Benefit Plan

The Secretary, in consultation with actuaries and other experts, must develop at least three actuarially sound benefit plans from which eligible individuals may choose. These benefit plans must conform to requirements governing premiums, benefits and other aspects of the program. Premiums must be based on an actuarial analysis of the 75-year costs of the program to ensure solvency throughout that period. For individuals with incomes below the poverty line and full--time students under age 22 who are actively employed, monthly premiums cannot exceed $5, plus increases pursuant to the consumer price index. Once the program has been operating for 10 years, the Secretary must adjust the premium amount based on an actuarial

[42] The HHS Secretary must promulgate regulations specifying exceptions to these minimum earning requirements for certain populations.

analysis of how much is needed to maintain reserves in the CLASS Independence fund. PHSA § 3203(a).

There is a five-year vesting period. PHSA § 3203(a)(1)(B). Benefits are triggered for enrollees when a licensed health care practitioner certifies that:

- an individual cannot perform a minimum number of activities of daily living[43] (either two or three) without substantial assistance;
- the individual has substantial cognitive impairments that requires substantial supervision to protect the individual from threats to health and safety; or
- has a level of functional limitation similar to either of these, as determined by regulations prescribed by the Secretary. PHSA § 3203(a)(1)(C).

The cash benefit must be no less than an average of $50 per day and be determined based on the level of functional limitation. There must be at least two levels of benefit payments and no more than six. It may be paid daily or weekly and cannot be subject to any lifetime limit. It must be coordinated with any supplemental coverage purchased through an exchange. PHSA § 3203(a)(1)(D).

The premium for a particular enrollee must remain the same as long as the individual is an active enrollee subject to certain exceptions. Premiums may be re-calculated to preserve the solvency of the program but must maintain a nominal premium for low-income individuals. In addition, enrollees who are age 65 or older, or who have paid premiums into the program for at least 20 years, or who are not actively employed, are exempt from any monthly premium increase. Premiums may be recalculated if an individual re-enrolls after a lapse of more than three months. PHSA § 3203(b)(1)(B).

Enrollment and Dis-Enrollment Requirements

The HHS Secretary, in coordination with the Treasury Secretary, is required to establish procedures through which an employer may automatically enroll an individual in the CLASS program, similar to those governing enrollment in a 401(k) or similar plan. Procedures must also be established for individuals who are self employed, have more than one employer, or whose employer does not elect to participate in the program. PHSA § 3204(a). Such procedures must allow individuals to opt out. PHSA § 3204(b). Individuals who are patients in institutional settings paid for by Medicaid or who are inmates in a penal institution are not eligible for automatic enrollment. PHSA § 3204(c). For individuals who are subject to automatic enrollment, a payroll deduction will be made by their employer, and the Secretary must create alternative procedures for individuals who do not earn wages or derive self-employment income or who are with employers who will not deduct. PHSA § 3204(e). The Secretary must also establish other enrollment and dis-enrollment opportunities. PHSA § 3204(g).

Benefits

[43] Activities of daily living are defined as eating, toileting, transferring, bathing, dressing, and continence. PHSA § 3202(3).

The Secretary must establish procedures for application and determination of eligibility, including establishing an Eligibility Assessment System that will provide for eligibility assessments. The Secretary must also promulgate regulations to develop an expedited national eligibility determination process. The eligibility process must include a process for determining presumptive eligibility. Pursuant to this process, an active enrollee will be deemed presumptively eligible if the individual has applied for and attests to be eligible for the maximum cash benefit and is:

- a patient in an institutional setting (nursing facility, intermediate care facility for the mentally retarded, institution for mental diseases, or hospital on a long-term basis); and
- about to be, or in the process of planning to be, discharged from an institutional setting, or is within 60 days from the discharge from the hospital. PHSA § 3205(a).

Several types of benefits are available through the CLASS program:

- cash with which to purchase non-medical services and supports necessary to maintain independence;
- advocacy services; and
- advice and assistance counseling. PHSA § 3205(b).

The Secretary must establish procedures for administering the provision of benefits, including payment of cash benefits into a Life Independence Account for each individual beneficiary. Specific services that may be purchased with funds from the Account include, but are not limited to:

- home modifications;
- assistive technology;
- accessible transportation;
- homemaker services;
- respite care;
- personal assistance services;
- home care aides; and
- respite.

The Secretary must also establish procedures for electronic management of funds. PHSA § 3205(c)(1).

Special payor rules apply for individuals enrolled in Medicaid. Institutionalized individuals (residing in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases) may retain five percent of their cash benefit, while the remainder goes to the Medicaid agency to cover the cost of services provided. Medicaid will then provide secondary coverage for remaining costs of care. Individuals will still receive the personal needs allowance provided under Medicaid. Enrollees or beneficiaries receiving home and community-based services will be allowed to retain 50 percent of their cash benefit. Medicaid will provide secondary coverage for any additional costs incurred in covering services.

The remaining 50 percent of the cash benefit will be paid to the state only if the waiver in which the enrollee is participating does not include waivers of statewideness and comparability. Individuals enrolled in Programs of All-inclusive Care for the Elderly (PACE) are subject to the 50-50 split if living in the community and the 95-5 split if living in an institution. PHSA § 3205(c)(1)(D). Benefits received under the CLASS program must supplement, and not supplant, other federally funded health care benefits or assistance to which an individual is entitled. PHSA § 3205(c)(7).

Benefits must be paid by the first month in which an application is approved. PHSA § 3205(c)(3). They must not have any effect on eligibility for other federal, state, or local program, including Medicaid, Medicare, SSI, SSDI, and CHIP. PHSA § 3205(f).

Additional provisions apply to the responsibilities of the Protection and Advocacy System for the state to assign counselors and provide information and assistance, and to the responsibilities of entities providing advice and assistance counseling, as well as procedures to protect against conflicts of interest with entities providing advice. PHSA § 3205(d), (e).

Class Independence Fund and Advisory Council

The legislation establishes a CLASS Independence Fund, consisting of all payments into the fund and income derived from their investment. The funds must be used to pay cash benefits, administrative expenses and investment on behalf of enrollees. The fund will be managed by the Treasury Secretary and overseen by a Board of Trustees, who must report to Congress and the public about the income and actuarial soundness of the Fund. PHSA § 3206.

An Independence Advisory Council (IAC) is also established, composed of 15 Presidential appointees who have experience with disability and technical issues relevant to the fund, and represent workers, individuals with disabilities and family caregivers. The IAC advises the HHS Secretary on administration of the fund and the formulation of regulations. PHSA § 3207.

The Secretary must also consult with the Board and IAC to ensure that the Fund and the program are solvent. No taxpayer funds may be used to pay benefits. PHSA § 3208. The Inspector General of HHS is required to submit an annual report describing progress of the program and the existence of any fraud, waste or abuse. PHSA § 3209.

Medicaid Act Amendments

The Medicaid Act is amended by adding a provision requiring that the state comply with regulations governing primary and secondary payor rules of individuals enrolled in both Medicaid and a CLASS program. PPACA § 8002(a)(2), *to be codified at* 42 U.S.C. § 1396a(a)(81).

This section requires states to assess, no later than two years after the date of the enactment of the CLASS program, the extent to which providers of personal care and similar services are serving as fiscal agents for individuals receiving benefits under the CLASS program.

States must also, within two years, designate or create entities to serve as fiscal agents, employers, or providers of benefits to ensure an adequate supply of benefits. It must also ensure that creating such entities will not negatively affect existing programs for self-directed care. § 8001(b), *to be codified at* 42 U.S.C. § 1396a(a)(82).

Not later than 90 days from enactment of the Act, a personal care attendant workforce advisory panel is established to advise the Secretary and Congress on workforce issues related to personal care attendant issues. PPACA, § 8001(c), *amending* § 6021 of the DRA of 2005, *to be codified at* 42 U.S.C. § 1396p note. This subsection is effective on June 21, 2010.

The CLASS Act will fill a significant gap in our insurance system. Long term care services, particularly nursing homes, are extremely expensive. Yet only the most limited coverage for these services is available through Medicare and private health insurance. Private insurance is prohibitively expensive and generally excludes people with certain disabling conditions. Medicaid covers nursing home and community-based services but only for those with very low incomes. Thus, people with middle and higher incomes are ineligible or must spend themselves into poverty to qualify. The CLASS Act will provide a realistic, accessible, and affordable option for aging individuals or those with disabilities.

Effective date: January 1, 2011, except § 8002(c), which is effective on June 21, 2010.

TITLE IX—REVENUE PROVISIONS

Additional Requirements for Charitable Hospitals, PPACA § 9007, § 10903

Hospitals and other health facilities can apply for tax-exempt status under § 501(c)(3) of the Internal Revenue Code. 26 U.S.C. § 501(c)(3). Charitable hospitals, also known as nonprofit hospitals, are exempt from paying state and federal income taxes and often receive other state benefits such as exemptions from paying property taxes. Contributions to nonprofit hospitals and health facilities are tax-deductible to donors.

The Internal Revenue Code imposes certain requirements on charitable hospitals as a condition of granting tax-exempt status. For example, charitable hospitals are required to provide "community benefits." The PPACA adds additional requirements as they relate to meeting community needs, free and low-cost care, billing and collections, and reporting. In addition, there are new penalties for failing to comply with the charitable hospital requirements. PPACA § 9007 (adding a new section 26 U.S.C. § 501(r)).

Charitable hospitals must conduct a community needs assessment every three tax years, and the assessment must reflect input from community stakeholders and made widely available to the public. In addition, the hospital must have an implementation strategy for meeting the needs identified in the assessment. PPACA § 9007 (adding 26 U.S.C. § 501(r)(3)). The hospital must report how it is meeting the needs of the community, and describe any needs that are not being addressed and the reasons. PPACA § 9007 (adding 26 U.S.C. § 501(r)(15)).

The PPACA requires charitable hospitals to have a written financial assistance policy that includes eligibility criteria, whether free or discounted care is available, how charges to patients are calculated, and the process for applying for financial assistance. The hospital must also have a written policy to provide emergency medical care regardless of the patient's ability to pay. The charges to patients who are eligible for financial assistance must be no more than the amounts generally billed to patients who have insurance coverage. PPACA § 10903(a) (amending 26 U.S.C. § 501(r)(5)).

Amendment to the Internal Revenue Code of 1986, PPACA § 9007
Sec. 4959 – Taxes on Failures by Hospital Organizations

For the first time, charitable hospitals can be assessed a tax of $50,000 for any year in which they fail to comply with the charitable hospital requirements. PPACA § 9007(b)(1). The Secretary of the Treasury is required to review the community health needs assessment of each charitable hospital every three years, and submit a report to certain Congressional committees annually on levels of charity care provided, bad debt, and costs of uncompensated care. In addition, the Secretary of the Treasury in consultation with the Secretary of Health and Human Services must conduct a study of trends in levels of charity care, and report to certain Congressional committees no later than five years after the enactment of the PPACA. PPACA §§ 9007(c), (e).