

## **Rockefeller-Brown Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Medicaid Managed Care Responsibility and Equity Act (S. 1787)

**Description:** The amendment would require a national MLR standard for Medicaid Managed Care Plans of 85/15.

The ratio is determined by taking expenses for incurred claims and quality improvement and dividing that amount by the total revenue for the plan under the plan contract. The amendment defines “quality improvement activities” similarly to the MLR requirements in statute. It adds definitions for “social determinants of health” and “patient engagement” to allow for MCOs to deduct the cost of value-added benefits to beneficiaries to their Medical costs in the numerator. It provides for a lower MLR ratio of 80/20 for managed care plans that have more than 10% CHIP enrollees. It provides authority for the Secretary to issue waivers. It provides for rebates to the state and federal Medicaid programs in the same proportion as the FMAP for that state.

## **Rockefeller-Nelson-Brown Amendment #2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Medicare Drug Savings Act (S. 740)

**Description:** This amendment reinstates the drug rebates received by Medicare beneficiaries, through the Medicaid program, prior to the creation of the Medicare prescription drug program.

When Medicare's prescription drug program was established, drug companies no longer had to provide these discounted prices to this population. This transition resulted in windfall profits for prescription drug manufacturers, at taxpayers' expense.

By simply returning discounted pricing to this population, this wasteful spending is ended, providing the opportunity to use those resources more wisely. This measure saves taxpayers an estimated \$141.2 billion over the next ten years, according to the Congressional Budget Office, more than enough to fully pay-for the repeal of the SGR and other improvements within the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013.

Starting January 1, 2015, manufacturers would be required to pay the difference between the lowest current rebates they are paying to private Part D drug plans, and the percentage of Average Manufacture Price (AMP) they currently pay under Medicaid, plus an additional rebate if their prices grow faster than inflation.

**Rockefeller Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Fair Hospital Competition Act of 2013 (S. 1791)

**Description:** The Fair Competition for Hospitals Act is targeted, budget-neutral legislation that would ensure that hospitals in the same Core-Based Statistical Area (CBSA) receive the same wage index.

There are currently 55 multi-state CBSA's, many of which contain hospitals in two to four states. As a result of various state exceptions, there can be a large discrepancy in reimbursement rates for hospitals that serve the same population but are on opposite sides of a state line.

**Rockefeller-Brown Amendment #4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Transitional Medical Assistance Substitution and Improvement

**Description:** This amendment would extend the existing TMA program, in which all states are providing TMA for six or twelve months, for 5 years but offers states additional flexibility to opt out of the program.

States that take the option to expand Medicaid and implement continuous eligibility (12 month) in their Medicaid program may opt out of the TMA requirements in both Section 1902 and Section 1925 of the Social Security Act.

## **Rockefeller-Grassley Amendment #5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Transitional Medical Assistance (TMA) Study, Substitution and Improvement

**Description:** This amendment would extend the existing TMA program, in which all states are providing TMA for six or twelve months, for 5 years but offers states additional flexibility to opt out of the program.

States that take the option to expand Medicaid and implement continuous eligibility (12 month) in their Medicaid program may opt out of the TMA requirements in both Section 1902 and Section 1925 of the Social Security Act.

This amendment would instruct MACPAC to undertake a study of churning including amongst individuals eligible for transitional medical assistance (TMA). One of the challenges in making decisions about longer-term policy on transitional medical assistance is the lack of information related to the income of individuals eligible for the benefit. As an individual's income changes, the individual's eligibility for Medicaid or TMA may change several times over a twelve to 24 month period. Understanding the volatility in income for these individuals will be helpful in informing future policy making.

Under this amendment, HHS and CMS will be instructed to provide data regarding TMA participants for the production of this report.

**Rockefeller-Grassley-Stabenow Amendment #6 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Creating Qualifying Option in All-Payer Revenue Approach for Partial Qualifying APM Participants

**Description:** Providers falling short of the APM incentive payment threshold by 5% or less will still qualify for the bonus if the provider demonstrates to CMS in a timely manner that 10% of its revenue is from Medicaid.

## **Rockefeller-Brown Amendment #7 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** To make permanent the Qualified Individual Program (QI) for qualifying Medicare beneficiaries.

**Description:** The Qualified Individual Program pays Medicare Part B premiums for low-income beneficiaries with incomes between 120 and 135 percent of the Federal Poverty Line and with limited assets.

Beneficiaries who qualify for QI also receive the Part D low-income subsidy to help with drug costs. Without this program, many Medicare beneficiaries would lose access to doctors outside of hospital stays as well as lose their Part D drug coverage. Also, Medicare providers in out-patient settings would experience a reduced patient population.

Rather than the five year extension contained in the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013, this amendment aligns the QI program with the new payment structure for Medicare providers by making it permanent. This keeps premium assistance and physician payment together as they have been historically.

## **Wyden-Isakson Amendment # 1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: The Better Care, Lower Cost Delivery System for Medicare Beneficiaries with Multiple Chronic Conditions

Description of Amendment: Amends Sec. 102 of the Chairman's Mark to include a new "Better Care Program" (BCP) as an eligible Advanced Payment Model. A health plan or group of providers that meet criteria related to patient satisfaction and engagement, quality measurement focused on multiple chronic conditions, and effective use of resources may participate as a BCP under a risk-adjusted capitated financial arrangement. Implementation of the BCP must focus on the nuances of a chronically ill Medicare population, as well as calculate long-term cost savings based on the entity's ability to deliver the full continuum of covered services including the physical, behavioral, and psychosocial needs of those eligible to enroll.

Health Plans or groups of providers shall use multidisciplinary teams to execute a model of care that includes an individual, personalized care plan for each enrollee, tailored to address the health risks determined by a thorough health and functional risk assessment. The use of telemedicine and appropriate health information technology is encouraged to implement that model of care.

Beneficiaries who enroll in the Better Care Program will be incentivized to actively manage their health by receiving value-based insurance benefits that encourage the use of high-value services aimed at driving better outcomes for those enrolled.

The Secretary shall give preference for participation to eligible BCPs that seek to practice in rural and/or underserved areas of the country, as well as in counties or regions that have a higher-than-average instance of high-cost chronic disease.



**Wyden-Isakson Amendment # 2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: Prioritizing Chronic Care Delivery

Description of Amendment: Amends Sec. 102 of the Chairman's Mark to include capitated models that specialize in treating the chronically ill as "eligible APMs." Such models would operate under capitated arrangements with networks made up of multidisciplinary teams that have experience managing the needs of these high risk beneficiaries.

**Wyden-Isakson-Carper-Grassley Amendment # 3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: An Amendment to Improve Medicare Advantaged Risk Adjustment

Description of Amendment: Requires the Secretary of Health and Human Services to adopt recommendations issued in MedPAC's June 2012 report calling for the use of two years of diagnosis data, inclusion of the number of conditions, and separating duals into full and partial duals to increase payment accuracy in the CMS-hierarchical condition category (CMS-HCC) model used for Medicare Advantage risk adjustment.

**Wyden-Isakson Amendment # 4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: An Amendment to Provide Chronic Condition Special Need Plans with Enhanced Benefit Flexibility

Description of Amendment: Amends Sec. 206 to require the Secretary of Health and Human Services to permit Chronic Condition-Special Need Plans (C-SNPs) enhanced flexibility to offer optional supplemental medical and/or behavioral benefits, which are tailored to and support the unique needs of the eligible population and demonstrate the ability to prevent, delay or minimize disease and disability progression. Such additional benefits may include secondary or tertiary medical and/or behavioral health items or services, but must: (1) relate do the beneficiary's primary diagnosis, and (2) be budget/rate neutral to rebate dollars in order to be allowable.

**Wyden Amendment # 5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: Promoting Unified Medicare and Medicaid Appeals Procedures

Description of Amendment: Amend Sec. 206 of the Chairman's mark to require the Secretary of Health and Human Services to consider applying the unified Medicare and Medicaid appeals procedures to other types of SNPs in addition to D-SNPs.

**Wyden-Grassley Amendment # 6 to the SGR Repeal and Medicare Beneficiary Access  
Improvement Act of 2013**

Short Title: An Amendment to Improve and Modernize Medicaid Data Systems and Reporting

Description of Amendment: A lack of consistency in state-reported information on Medicaid continues to be an ongoing issue that limits the usefulness of federal data for analytic and oversight purposes (*see* MACPAC's March 2011 report to Congress). To ensure that CMS takes the appropriate and necessary steps to address redundancies and gaps in Medicaid data, CMS should implement a strategic plan to address such redundancies and gaps through improvement and modernization of computer and data systems and reporting. Areas for improvement shall include, but are not limited to: the reporting of encounter data by managed care plans, the timeliness and quality of enrollment and other data, consistency of data across sources, and information about state program policies. The Secretary shall report on the implementation status no later than July 1, 2014.

**Wyden-Crapo Amendment # 7 to the SGR Repeal and Medicare Beneficiary Access  
Improvement Act of 2013**

Short Title: To provide transparency for adding procedures to the Medicare Ambulatory Surgery Center List

Description of Amendment: Currently, Medicare only reimburses ASCs for procedures explicitly identified in regulation by CMS. CMS is regularly receives requests to add procedures to the ASC list, as the agency may update its list annually. CMS is required to judge the safety of outpatient surgical procedures but can exclude procedures from the list for any reason. CMS does not provide any basis (clinical or otherwise) for its decisions. This amendment would provide transparency to this process by requiring CMS to disclose during the rulemaking process which safety criteria triggered the procedure exclusion.

**Wyden Amendment # 8 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

Short Title: An Amendment to Include S. 562: Seniors Mental Health Access Improvement Act of 2013 in the Chairman's Mark.

Description of Amendment: S. 562 amends title XVIII (Medicare) of the Social Security Act to provide for coverage of marriage and family therapist services and mental health counselor services under Medicare part B (Supplementary Medical Insurance), particularly those provided in rural health clinics, federally qualified health centers (FQHCs), and in hospice programs. Amends Medicare part C (Miscellaneous) to exclude such services from the skilled nursing facility (SNF) prospective payment system. Authorizes marriage and family therapists and mental health counselors to develop discharge plans for post-hospital services.

**Wyden-Portman-Carper-Enzi Amendment # 9 to the SGR Repeal and Medicare  
Beneficiary Access Improvement Act of 2013**

Short Title: An Amendment to Include S. 1228: Medicare Better Health Rewards Program Act of 2013

Description of Amendment: The Medicare Better Health Rewards is a three-year wellness program that uses the annual wellness visit Medicare already pays for to ascertain and measure improvements in six key areas of health: tobacco usage; body mass index; diabetes indicators; blood pressure; cholesterol; and, up-to-date vaccinations and screenings. These areas have been identified by experts as leading predictors of future health challenges.

According to the Centers for Medicaid and Medicare Services, more than 3 million seniors took advantage of Medicare's free annual wellness visit last year.

First-year participants would be assessed in each of these areas and then work with their doctor to develop a plan to bring those indicators into a healthier range. Progress would be measured during subsequent wellness visits in years two and three of the program. Participants who achieve and maintain their indicator targets would be eligible for up to \$200 after their second visit and up to \$400 after their third visit.

Under the program, the Centers for Medicare and Medicaid Services (CMS) will calculate savings by deducting the actual cost of seniors enrolled in the program from the total projected costs of those participating absent the program.



**Wyden Amendment # 10 to the SGR Repeal and Medicare Beneficiary Access  
Improvement Act of 2013**

Short Title: An Amendment to Improve Medicare Advantage Benchmark Rate Calculation

Description of Amendment: CMS currently determines county benchmarks using fee-for-service data. As Medicare Advantage penetration increases, relying on Medicare part A & B data alone may skew the benchmark calculation. To ensure that benchmarks are representative of the Medicare population in that service area (county, whatever region as determined appropriate by the Secretary), CMS should calculate the benchmark by including MA encounter data once a county's MA penetration exceeds 25%.

## **Schumer - Grassley Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:**

Rural Hospital Access Act

**Purpose:**

To permanently extend the Medicare Dependent Hospital program and the Low Volume Hospital program

**Background:**

The Omnibus Budget Reconciliation Act of 1989 (P.L.101-239) created a new Medicare Dependent Hospitals (MDHs) program that made small, rural hospitals eligible for additional payments. The MDH program lapsed in 1994 and was reinstated by the BBA. The program has been extended periodically and changed by subsequent legislation. The MDH special payment status expired on September 30, 2013.

MDHs are small rural hospitals with a high proportion of patients who are Medicare beneficiaries. MDHs have no more than 100 beds and at least 60 percent of acute inpatient days or discharges attributable to Medicare in FY1987 or in two of the three most recently audited cost reporting periods. Specifically, an MDH hospital will be paid the national prospective payment service (PPS) rate plus a percentage difference between that amount and a hospital-specific cost per discharge amount from a given year. Before October 1, 2006 an MDH received 50 percent of the difference between the base rate and its adjusted hospital-specific costs. Since October 1, 2006, an MDH has received 75 percent of the difference between the base rate and its adjusted hospital-specific costs.

Under the Medicare IPPS, certain low-volume hospitals receive a higher payment amount to account for their higher costs per discharge in Fiscal Year 2012 and Fiscal Year 2013. The adjustment operates on a sliding scale with hospitals having fewer than 200 Medicare discharges receiving a 25 percent payment increase, decreasing on a sliding scale to 0 percent for hospitals with more than 1,600 Medicare discharges. These hospitals must be located more than 15 miles or more from another comparable hospital. This adjustment expired on September 30, 2013.

The low-volume adjustment is based on the concept that large hospitals benefit from certain economies of scale that are not available to small hospitals with limited discharges.

**Description of Amendment:**

This amendment would permanently extend the Medicare Dependent Hospital program and the Low Volume Hospital program.

## **Schumer Amendment #2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

### **Short Title:**

Delay Medicaid Disproportionate Share Hospital (DSH) Cuts for Two Years and Avoid Extraordinary Losses from Medicare DSH Cuts

### **Purpose:**

To delay Medicaid Disproportionate Share Hospital (DSH) cuts for two years and avoid extraordinary losses from Medicare DSH cuts

### **Background:**

The Medicare and Medicaid programs provide supplemental funding to DSH hospitals that serve a significant share of patients with severe socio-economic challenges. Hospitals generally provide services to such patients at a significant loss because they are uninsured or on Medicaid, and their treatment requires above-average resources due to many factors.

The Affordable Care Act made changes to the Medicaid and Medicare DSH programs that took effect in fiscal year (FY) 2014. The Medicaid changes cut overall DSH payments based on states rates of uninsurance and the extent to which they target DSH dollars to hospitals with high levels of Medicaid patients or uncompensated care. The Medicare policy maintains 25% of DSH payments and then cuts and redistributes the remaining 75% based on a measure of hospital uncompensated care.

### **Description of Amendment:**

This amendment would delay the Medicaid DSH cuts by two years to FY 2016. It would also institute a stop-loss policy relating to the Medicare DSH cuts in FYs 2014 and 2015 and to authorize, but not require, HHS to establish a pool of DSH funds for stop-loss relief in any subsequent year.

The stop loss policy for FY 2014 would allocate \$450 million to cap individual hospital losses at approximately \$4 million or 2% of DSH-adjusted base inpatient payments (wage and case-mix adjusted aggregate inpatient payments). The policy for FY 2015 would allocate \$550 million to cap losses at approximately \$6.8 million or 3.4% of such payments.

In FY 2016 and beyond, the Secretary could set aside up to 10% of uncompensated care payments to finance a stop-loss pool for hospitals standing to receive substantial reimbursement cuts under the new DSH policy. As with FYs 14 and 15, stop-loss payments would be based on capping hospital-specific losses in DSH-adjusted base inpatient payments at both a hard dollar and percentage level, with the latter necessary to protect smaller hospitals.

**Schumer Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of  
2013**

**Short Title:**

Home Health Care Planning Improvement Act

**Purpose:**

To authorize nurse practitioners to certify patient eligibility for Medicare home health services.

**Background:**

Today's nurse practitioners (NPs) play an increasingly important role in managing and delivering health care to Americans. NPs are recognized under state laws and regulations to complete and sign physical examination forms and other medical certification documents. Since 1998 NPs have been authorized Part B Medicare providers, recognized to furnish, order and refer for services under their provider numbers. NPs order physical therapy, occupational therapy, bill as consultants and consultees when providing services through telemedicine, order and bill for performing and interpreting diagnostic tests within their scope of practice, and certify patients eligible for skilled nursing care. They may also bill for services as attending providers and for services "incident to" their own service.

Nurse practitioners have demonstrated the ability to deliver safe, cost-effective, and responsible care to the patients they serve. They have expert knowledge that allows them to provide high-level assessments of patient needs and recognize when additional care such as home health care is needed. Given their proven track record and the authorization of the Balanced Budget Act of 1997 for the care of seniors and the disabled, it is illogical and impractical that nurse practitioners are recognized as Part B Medicare providers but are still unable to document face-to-face patient assessments and certify home health care plans of care for their patients.

Currently, nurse practitioners with patients who need home health care services must locate a physician who will document the nurse practitioner's assessment for this care. Further, even though NPs are authorized to perform a face-to-face assessment of the patient's needs, the Affordable Care Act now requires that a physician document the encounter has taken place – even if the physician is not involved in the assessment. Not only is the health of the patient jeopardized by the delays in treatment that these requirements create, the Medicare program also incurs additional costs by requiring the participation of additional providers with reimbursement rates higher than those of nurse practitioners.

**Description of Amendment:**

This amendment would authorize nurse practitioners to certify patient eligibility for Medicare home health services.

## **Schumer - Grassley Amendment #4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

### **Short Title:**

Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act

### **Purpose:**

To define doctors of podiatric medicine (DPMs, or podiatrists) as “physicians” in the Medicaid program.

### **Background:**

Podiatric physicians and surgeons are licensed by their state boards to prescribe medication and perform surgeries, and deliver independent medical and surgical care without any supervision or collaboration requirement.

Under current law, foot and ankle care services are a covered benefit. However, when those services are provided by doctors of podiatric medicine (DPMs, or podiatrists) they can be teased out as “optional” coverage (“podiatry services”). This problem persists because podiatrists are not defined as “physicians” under Medicaid even though they have been defined as such under Medicare for more than 40 years.

The amendment would not mandate new Medicaid services or benefits, nor would it require any Medicaid patient to seek care from a podiatric physician. It would not expand the scope of practice. It would simply provide that Medicaid patients have a full range of choices to see the physicians who are best trained for the foot and ankle care they seek.

The current processes and Medicare contractor requirements for determining eligibility for Medicare’s Therapeutic Shoe Program for patients with diabetes, and for furnishing this medically necessary benefit, are unnecessarily burdensome and frequently bogged down, leading to frustration on the part of the certifying physician, prescribing doctor, and supplier. The clarifications in the legislation would remove confusion and regulatory inconsistencies in the provision of this medically necessary benefit.

### **Description of Amendment:**

This amendment would define doctors of podiatric medicine (DPMs, or podiatrists) as “physicians” in the Medicaid program. The amendment would also clarify Medicare documentation requirements for therapeutic shoes for persons with diabetes. The clarifications would statutorily recognize the prescribing podiatrist’s (and other qualified physician’s) lower-extremity examinations, determination of foot pathology, and the medical necessity for therapeutic shoes/inserts when making a case (to CMS and auditors) for qualifying Medicare’s therapeutic shoe and insert benefit for their patients with diabetes.

## **Schumer - Crapo Amendment #5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

### **Short Title:**

Cardiac and Pulmonary Rehabilitation

### **Purpose:**

To allow physician assistants, nurse practitioners, and clinical nurse specialists to supervise cardiac, intensive cardiac and pulmonary rehabilitation programs.

### **Background:**

Cardiac and pulmonary rehabilitation are medically directed and supervised programs designed to optimize a patient's physical, psychological, and social functioning. Programs utilize physician prescribed, supervised exercise, risk factor modification, education, counseling, behavioral intervention, psychosocial assessment and outcomes assessment. These programs are evidence-based, multidisciplinary, and comprehensive interventions for patients with chronic and acute cardiac and respiratory diseases. Integrated into the individualized treatment of the patient, rehabilitation is designed to reduce symptoms, optimize functional status, increase activity, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease. Programs supply an individualized and personalized treatment plan, including evaluation and instruction on physical activity, nutrition, stress management, and other health related areas. Provision of these services is physician-directed and implemented by a multi-disciplinary team of healthcare professionals, which may include nurses, exercise physiologists, respiratory therapists, dietitians, health educators, behavioral medicine specialists, and other healthcare professionals.

Central to both cardiac and pulmonary rehabilitation is the role of the physician. Programs are required to have a Medical Director. The Medical Director is ultimately responsible to assure that all systems are in place to facilitate the entire process of cardiac or pulmonary rehabilitation. The primary roles of the Medical Director, as leader of the multidisciplinary team, are to assure that the rehabilitation program is safe, comprehensive, cost effective, and medically appropriate for individual patients. Additionally, programs must have a supervising physician (or NPP) available for each session, to respond to emergencies. This individual is only responsible to respond if an emergency arises, and has no other responsibility in the program.

Under current policy, CMS will not permit non physician practitioners to supervise these programs, arguing that the current statute precludes such flexibility.

### **Description of Amendment:**

This amendment would allow physician assistants, nurse practitioners, and clinical nurse specialists to supervise cardiac, intensive cardiac and pulmonary rehabilitation programs.

## **Schumer Amendment #6 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

### **Short Title:**

Ensuring Access to Quality Complex Rehabilitation Technology Act

### **Purpose:**

To create a separate benefit category for complex rehabilitation technology within the Medicare program.

### **Background:**

Complex rehab technology is critical to the quality of life and independence of many people living with disabilities, including individuals with significant medical conditions like cerebral palsy, muscular dystrophy, multiple sclerosis and spinal cord injuries. Complex rehab technology includes medically necessary, individually configured manual and power wheelchair systems, adaptive seating systems, alternative positioning systems, and other mobility devices that require evaluation, fitting, design, adjustment and programming. This type of technology is designed to meet the specific and unique medical and functional needs of an individual living with disability.

Medicare currently does not have unique coverage for the more complex equipment that so many people rely upon. These specialized products are currently included within Medicare's broad durable medical equipment (DME) benefit category which does not provide adequate differentiation of CRT devices and prevents focused policies and safeguards. A separate benefit category for CRT will provide appropriate segregation to better address the unique needs of individuals with disabilities and chronic medical conditions who require these specialized products. This will allow for needed improvements in coverage policies, coding, and quality standards.

Congress has previously acknowledged that complex rehab power wheelchairs are unique and more specialized than standard DME. In 2008, legislation was passed exempting these products from inclusion in Medicare's DME competitive bidding program recognizing that such inclusion would jeopardize access to this customized technology. In addition, Congress has recognized the unique nature of other customized products and services and created a separate classification for Orthotics and Prosthetics (O&P), i.e. custom braces and artificial limbs. The Centers for Medicare and Medicaid Services (CMS) acknowledged the specialized service component inherent in custom-fit orthotics and prosthetics and treats O&P as separate and unique with its own medical policies, accreditation standards, and reimbursement calculations. This same distinct recognition is needed for Complex Rehab Technology.

### **Description of Amendment:**

This amendment would create a separate benefit category from the current DME category to allow for targeted Medicare policies on complex rehabilitation technology (CRT) and for improved oversight.

It would also separate out billing codes for items classified as CRT and create new billing codes for CRT items currently included in broader codes. For any new billing codes created, the

Secretary of Health and Human Services would establish a new payment system, taking into account the unique needs of beneficiaries who need CRT items and the resources and staff needed to provide appropriate customization of CRT items.

It would also establish clinical conditions for coverage that ensure these items are being prescribed appropriately, which would include that for any CRT wheelchair, an evaluation be conducted by a licensed physical or occupational therapist with no financial relationship to the CRT supplier. CRT items would be exempt from Medicare's "in-the-home" restriction, which does not address a beneficiary's needs outside the home environment.

It would also improve program safeguards by increasing quality standards for suppliers of CRT items above current DME standards, including that each supplier must have qualified staff available to assist beneficiaries with training and repair for their CRT items. Suppliers must also be accredited by an independent accreditation organization demonstrating that they are compliant with these enhanced quality standards.

It would also allow beneficiaries in skilled nursing facilities to obtain CRT items if these items are part of a plan of care to allow them to transition from the skilled nursing facility setting to the home and community.



**Schumer Amendment #7 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of  
2013**

**Short Title:**

Puerto Rico Medicare Part B Equity Act

**Purpose:**

To apply “deemed enrollment” in Medicare Part B to residents of Puerto Rico and reduce the monthly late penalty that each beneficiary pays for enrolling late in Part B.

**Background:**

Puerto Rico is the only U.S. jurisdiction where individuals who become eligible for Medicare Part A are not automatically enrolled in Part B.

According to data provided by CMS, as of 2009 there were 52,936 individuals in Puerto Rico who are currently paying a lifetime penalty for enrolling late in Part B. In 2009, these late fees totaled \$7,011,133.

Also according to data provided by CMS, as of 2009 there were 130,846 individuals in Puerto Rico who were enrolled in Part A, but not enrolled in Part B. (Puerto Rico has, by far, the lowest Part B enrollment rate in the country.)

**Description of Amendment:**

This amendment would apply “deemed enrollment” in Medicare Part B to residents of Puerto Rico. It would also reduce the monthly late penalty that each beneficiary pays for enrolling late in Part B by 85%—that is, to 15% of what it would otherwise be. It would also authorize a special enrollment period during which individuals enrolled in Part A but not Part B could enroll in Part B and pay a late fee that is (again) 85% less than what they would otherwise pay. The special enrollment period lasts for seven months, beginning on the same month between October 2014 and January 2015 that the Secretary decides to use to make deemed enrollment effective.

## **Stabenow Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short title/purpose:** To improve quality, and expand access to community mental health services.

**Description of Amendment:** This amendment establishes a 5 year demonstration program for up to 10 states to set new criteria for community behavioral health providers, and allow them to be reimbursed for a broad range of services. The Secretary of Health and Human Services, in coordination with the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), would award planning grants to the selected states.

To be eligible, states would have to certify that providers of community mental health services meet new criteria and offer specific behavioral health services. Those services would then be reimbursed under Medicaid using a Prospective Payment System (PPS) based on the PPS for Federally Qualified Community Health Centers under section 1902(bb) of the Social Security Act. Those services would also be eligible for an enhanced Federal Match rate as defined under section 2105(b), the same rate as the Children's Health Insurance Program.

The Administrator of CMS, in consultation with SAMHSA, will issue regulations for certifying community behavioral health clinics that meet the following criteria:

- Employ a core clinical staff that is trained to provide evidence-based practices and is multi-disciplinary and able to provide translational services when necessary;
- Demonstrate the capacity to comply with behavioral health and related healthcare quality measures promulgated by entities such as the National Quality Forum, the National Committee for Quality Assurance, or other nationally recognized accrediting bodies;
- Ensure that no patient will be denied mental health or other healthcare services due to an individual's inability to pay; and,
- Report required encounter data, clinical outcomes data, and quality data.

The clinics will have to provide the following services to the extent that they are covered in the state Medicaid plan under title XIX of the Social Security Act and the Early Periodic Screening, Diagnosis, and Treatment Program under section 1905(r) of the Social Security Act:

- Crisis mental health services including: 24-hour mobile crisis teams, emergency crisis intervention services, and crisis stabilization;
- Targeted case management;
- Peer support and counselor services and family supports;
- Screening, assessment, and diagnosis, including risk assessment;
- Outpatient mental health and substance use services including: psychotherapy, cognitive behavioral therapy, applied behavioral analysis, medication management, and integrated treatment for trauma, mental illness, and substance abuse which shall be evidence-based; and,
- Outpatient clinic primary care screening including screening for diabetes, hypertension and cardiovascular disease.

Where feasible, clinics would have to provide outreach and engagement, and intensive community-based mental healthcare for members of the armed forces and veterans, particularly those located in rural areas.

The clinics will also have to maintain linkages, and where possible enter into formal contracts, agreements, or partnerships with:

- At least one federally qualified health center;
- Department of Veterans Affairs medical centers, outpatient clinics, and inpatient hospitals;
- Inpatient psychiatric facilities and substance use and residential programs;
- Family support services for families of children with serious mental or substance use disorders; and,
- Other community or regional services, supports and providers including schools, criminal justice agencies, and therapeutic foster care placing agencies.

In selecting states for the demonstration, the Secretary will ensure the geographic diversity of participating states, including representation of certified clinics in rural and other underserved areas within those states. The Secretary will also take into account the ability of clinics to provide all the required services on a statewide basis. Finally, the Secretary would be required to submit an annual report to Congress on the demonstration program.

**Stabenow - Casey Amendment #2 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short title/purpose:** To clarify payments for drugs under Medicare Part B by excluding prompt pay discounts from Average Sales Price

**Description of Amendment:** This amendment would modify Medicare Part B, section 1847A(c)(3) of title XVIII of the Social Security Act, by excluding customary prompt pay discounts paid by manufactures to wholesalers for drugs and biologicals from the methodology for calculating Average Sales Price (ASP). This would harmonize reporting of pharmaceutical prices under ASP with the reporting under Average Manufacturer Price (AMP).

### **Stabenow Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short title/purpose:** To postpone the rebasing of home health payments to allow for further evaluation

**Description of Amendment:** This amendment would modify section 1895(b)(3)(A)(iii) of the Social Security Act to postpone the home health rebasing adjustment under 1895(b)(3)(A)(iii) for one year so that it would not take effect in 2014. In 2015, the rebasing adjustment for both 2014 and 2015 would take effect as it would under current law.

The amendment would also require the Secretary to submit a report to Congress by June 30<sup>th</sup>, 2014 evaluating the impact of the rebasing adjustment on beneficiary access to care in each year that it takes effect, and considering all alternative methods for determining the appropriate rebasing adjustment under section 1895(b)(3)(A)(iii). The Secretary must consult with home health stake holders including agency and beneficiary representatives in compiling the report.

The amendment would also modify section 1895(b)(5)(A) of the Social Security Act by reducing the home health outlier payment budget from 2.5 percent of the total payments projected or estimated to be made to 2 percent for years 2014 through 2023 to offset the cost of the postponement of the rebasing adjustment.

**CANTWELL AMENDMENT #1 to the Chairman's Mark (the SGR Repeal and Medicare Beneficiary Access Act of 2013)**

**Cantwell Amendment 1 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short Title:** To retain the weight of Quality and Resource Use performance categories in determining the score under the Value-Based Performance Program.

**Description of Amendment:** This amendment would give the Secretary the discretion to increase the weight for the Quality or the Resource Use performance categories of the Value Based Performance Program, but prevent the Secretary from reducing the Quality or Resource Use performance category weights below 30 percent each.

**Cost:** There is no cost for this amendment.

**CANTWELL AMENDMENT #2 to the Chairman's Mark**  
**(SGR Repeal and Medicare Beneficiary Access Act of 2013)**

**Cantwell Amendment 2 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short Title:** To include hospitals operating “under arrangement” in the definition of “inpatient hospital services” under the Inpatient Prospective Payment System.

**Description of Amendment:** This amendment expands Section 1395x of 42 U.S.C. §1395 to define the term “inpatient hospital services” as the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital--

**(1)** bed and board;

**(2)** such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

**(3)(A)** such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements; and

**(B)** with respect to a hospital described in section 1886(d)(1)(B)(v) [42 USC§ 1395ww(d)(1)(B)(v)] and located in the same building as or on the same campus as another hospital, items and services included in subsections (1) and (2) above, furnished by or to the hospital described in section 1886(d)(1)(B)(v) [42 USC§ 1395ww(d)(1)(B)(v)] under arrangements;

excluding, however. . .

42 USC 1395x(b).

**Cost:** This provision has not been scored.

**CANTWELL AMENDMENT #3 to the Chairman's Mark**  
**(SGR Repeal and Medicare Beneficiary Access Act of 2013)**

**Cantwell Amendment 3 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short Title:** To restore the Medicare Value-Based Payment Modifier.

**Description of Amendment:** This amendment would restore the Medicare Value-Based Payment Modifier as codified in 42 U.S.C. §1848 (p)(2) and (p)(3) and to set provider payment adjustment at 5 percent beginning in 2015. Gives the Secretary discretion to increase the Medicare physician performance payment adjustment up to 10 percent by 2020. Allows the Secretary to set a timetable for payment adjustment.

**Cost:** This provision has not been scored.



**CANTWELL AMENDMENT #4 to the Chairman's Mark**  
**(SGR Repeal and Medicare Beneficiary Access Act of 2013)**

**Cantwell Amendment 4 to the SGR Repeal and Medicare Beneficiary Access Act of 2013**

**Short Title:** To allow the Secretary discretion to perfect the Medicare physician Value-Based Payment Modifier.

**Description of Amendment:** This amendment would restore the Medicare Value-Based Payment Modifier as codified in 42 U.S.C. §1848 (p)(2) and (p)(3) and give the Secretary discretion to perfect the provisions of the Value-Based Payment Modifier.

**Cost:** This provision has not been scored.

**Nelson – Schumer – Stabenow – Menendez – Casey Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Residency Physician Shortage Reduction

**Description of Amendment:** This amendment is identical to S. 577. As our nation works to reform the health care delivery system and as more seniors enter the Medicare program, we must ensure there is an adequate supply of physicians to serve all communities.

The Secretary of Health & Human Services shall increase the number of residency slots by 3,000 each year from 2015 through 2019, of which at least 1,500 each year must be used for a shortage specialty residency program. The Secretary will use specific criteria to determine the distribution of the new slots.

## **Nelson – Grassley #2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Expansion of Medicaid Fraud Control Unit (MFCU) Federal Financial Participation (FFP) Eligibility

**Description of Amendment:** Currently, section 1903(q)(4) of the Social Security Act (Act) requires the Secretary of the Department of Health and Human Services to provide FFP for MFCUs that act upon complaints of abuse or neglect occurring in one of two settings: (1) Medicaid-funded “health care facilities” or (2) “board and care” facilities. However, the increase in Medicaid funded services provided outside of health care facilities has increased the scenarios under which a beneficiary will be the victim of abuse or neglect. Because of the specialized training, experience, and demonstrated success of the MFCUs in pursuing complaints of abuse and neglect in connection with the provision of health services, they commonly receive information about abuse and neglect in these settings.

This amendment would expand the scope of MFCU activities that are eligible FFP to include the costs of investigating and prosecuting allegations of abuse or neglect against Medicaid beneficiaries receiving services in non-institutional settings.

## **Nelson Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Part D Beneficiary Appeals Fairness

**Description of Amendment:** This amendment is identical to S.1365 and would extend the current right to appeal for a tiering exception for drugs on the specialty tier in Medicare Part D. Under the current Medicare Part D Appeals process, a tiering exception is a type of coverage determination where a beneficiary appeals to the plan to cover an on-formulary drug at the next-lowest tiered cost-sharing level, reducing the out-of-pocket cost. The beneficiary's physician must show that the specific drug in question is absolutely medically necessary to the beneficiary in order for the request to be considered and the plan determines whether to grant or deny the appeal on a case-by-case basis. Beneficiaries can request a tiering exception on every tier in their plan except for drugs on the specialty tier. Without a right of appeal, Medicare beneficiaries in need of a drug on a specialty tier have no recourse to request a reprieve from unaffordable out-of-pocket costs.

## **Nelson – Grassley – Rockefeller – Enzi Amendment #4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** To amend title XIX of the Social Security Act to empower individuals with disabilities to establish their own supplemental needs trusts

**Description of Amendment:** This amendment is identical to S. 1672. In 1993, as part of a reconciliation bill, Congress authorized special needs trusts, which are trusts to benefit a person with a disability that hold assets to provide funding for expenditures that would supplement, not supplant, benefits provided by Medicaid. For example, the trust could be used to pay for rent or other non-health essentials. The state can go after any funds remaining in the special need trust to recoup what it paid out in Medicaid benefits. The parent, grandparent, or legal guardian of a child with a disability can create the trust, but an adult with a disability cannot create the trust himself or herself.

This situation is problematic for an adult with disabilities if his or her parents or guardian have died without setting up such a trust. He or she would need to petition a court to create a trust, which can be complicated and expensive for a Medicaid beneficiary to pay for an attorney and court fees. Additionally, a court may appoint a trustee who has no relationship to the beneficiary.

This amendment would amend title XIX to allow the individual himself or herself to set up a special needs trust.

## **Nelson – Rockefeller – Casey Amendment #5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Annual Medicaid DSH Report

**Description of the Amendment:** The Centers for Medicare and Medicare Services have announced the methodology for calculating Medicaid Disproportionate Share Hospital (DSH) reductions for FY 2014 and FY2015 as required in the Affordable Care Act (ACA). To ensure that Congress has sufficient information to determine an appropriate level of DSH funding for the remaining years of scheduled DSH reductions, the amendment would require the Secretary of Health and Human Services (the Secretary) to report to Congress on an annual basis beginning on January 1, 2015. The report would contain the following elements:

- Changes in the number of uninsured individuals as compared to 2013 and compared to Congressional Budget Office estimates used at the time of ACA enactment;
- The extent to which hospitals continue to incur uncompensated costs for Medicaid patients and the uninsured;
- The extent to which hospitals continue to provide charity care and incur bad debt associated with Medicaid, the State Children’s Health Insurance Program, and state or local indigent care programs, as reported on Medicare hospital cost reports;
- In the first year, a methodology for estimating the amount of unpaid patient deductibles, copayments and coinsurance incurred by hospitals for patients enrolled in qualified health plans through a health insurance exchange, using existing data and minimizing the administrative burden on hospitals to the extent possible. Subsequent reports would include data collected pursuant to this methodology;
- For each state, the difference between the aggregate amount of hospital uncompensated care costs and the state’s DSH allotment;
- The extent to which there are certain vital hospital systems that are disproportionately experiencing high levels of uncompensated care, that have multiple other missions, such as a commitment to graduate medical education, the provision of tertiary and trauma care services, public health and essential community services and comprehensive, coordinated care; and
- Such other issues related to the determination of State DSH allotments under Medicaid as the Secretary of Health and Human Services determines appropriate.

## **Menendez-Brown Amendment #1 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Clarify the Two-Midnight Policy for Medicare Inpatient Determinations

### **Background**

Included in the 2014 final inpatient prospective payment system (IPPS) rule, CMS imposed a new “two midnight” rule that established new requirements regarding how Medicare covers short inpatient hospital stays. Under this new policy, beneficiary stays in the hospital that span “two midnights” or longer will continue to be billed as typical Medicare Part A inpatient care.

However, this new rule requires that hospital stays “shorter than two midnights” must be categorized as outpatient and billed under Medicare Part B, regardless of the patient’s severity of illness or the intensity of care they require. The current distinction does not take into account cases where a physician deems such an inpatient stay clinically necessary.

### **Description of Amendment**

This amendment will:

- Require CMS to seek advice and consultation from hospitals, physicians and other expert stakeholders to determine appropriate criteria to account for medically necessary inpatient admissions that last less than 2 midnights;
- Provide for a delay in the enforcement of the 2-midnight rule for any admission occurring prior to October 1, 2014.

## **Menendez-Brown Amendment #2 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Provide Transparency in the Clinical Laboratory Fee Schedule and Establish a Demonstration Program to Test Appropriate Use Criteria in Clinical Laboratory Services

### **Background**

Clinical laboratories perform tests which form the basis for 70 percent of all clinical decisions. Clinical lab services provided under Medicare Part B are reimbursed based on a Clinical Laboratory Fee Schedule (CLFS), which is updated annually to reflect inflation and multi-factor productivity adjustments. Recently CMS has initiated a process to reevaluate the value of all codes on the CLFS, which is a responsible step towards ensuring Medicare accurately reimburses providers for these services. However, when CMS identifies codes in need of substantial payment changes, a process needs to be in place to ensure labs are able to make the necessary changes to ensure beneficiaries have continued access to vital laboratory services.

Additionally, clinical laboratories are a prime testing ground for a demonstration program to evaluate the use of appropriate use criteria.

### **Description of Amendment**

To ensure full transparency in CMS's ongoing CLFS rate review process, this amendment would require that CMS make public all necessary and appropriate data used in determining changes in CLFS reimbursements. Additionally, any change in payment in excess of 10% shall be subject to a phase-in period to limit the payment reduction to no more than 10% per year. Finally, the amendment would require CMS consider all necessary data to ensure that changes in reimbursements adequately account for costs associated with servicing beneficiaries in various settings, such as those in home health and in skilled nursing facilities.

This amendment would also add a provision to Section 1115A of the Social Security Act to establish a demonstration project testing the application of appropriate use criteria for clinical laboratory services provided by independent clinical laboratories under Medicare Part B. Specifically, the demonstration would identify the 50 most common medical conditions and develop algorithms to determine the appropriate series of laboratory tests to be conducted, linking clinical laboratory test codes with medical diagnosis codes. Such criteria and subsequent reimbursement and billing processes for tests provided through this process will be determined through consultation with laboratories, physicians and other expert stakeholders. The goal of the demonstration is to evaluate a process to better guide physicians on which laboratory tests are needed to support clinical decision making, ensure Medicare is paying for the right tests to meet a diagnosis, establish efficiencies in the laboratory testing process, and improve the quality of patient care.



One year after completion of the demonstration, the Secretary will report to Congress on the demonstration's impact on access to care, quality of care, health outcomes and expenditures (including any savings) and recommendations to expand the demonstration.

## **Menendez Amendment #3 to the SGR Repeal and Beneficiary Access Improvement Act**

**Short Title** Providing for Better Targeted Assistance to Small Practices

### **Background**

The Chairman's Mark provides \$25 million in funding for technical assistance to small practices to help them participate in the value-based performance program or to transfer to an alternative payment model. The Chairman's Mark prioritizes this funding to practices of less than 10 eligible professionals and those in rural areas or health professions shortage areas (HPSAs). HPSAs are designated by the Health Resources Services Administration (HRSA) and take into account not only the provider-to-population ratio, but other factors such as geographic location. Medically underserved areas (MUAs) on the other hand, consider the population-to-provider ratio but also additional factors such as the area's poverty rate.

### **Description of Amendment**

This amendment makes a small technical change to the Chairman's Mark to ensure that providers in truly underserved areas are prioritized for technical assistance funding. Specifically, this amendment changes the qualification from a practice being located in a rural area or HSPA to one in a rural area or a medically underserved area (MUA). This change will more accurately target needed TA funds to providers in areas that are both facing provider shortages and have a substantial low-income population. The amendment does not change the mark's provision to also prioritize small practices in rural areas.

## **Menendez Amendment #4 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Correct for Misclassification Of A Bladder Cancer Drug in the 2014 Outpatient Prospective Payment System Rule

### **Background**

Bladder cancer affects more than 72,000 Americans a year and is responsible for more than 15,000 deaths. The disease disproportionately affects the Medicare population, with the average age of diagnosis at 73, and has an extremely high recurrence rate of between 50-75 percent. Recently, however, the FDA approved a new breakthrough technology that utilizes blue-light cystoscopy coupled with the drug Cysview. This technology allows physicians to more accurately remove cancerous cells from the bladder. By more thoroughly treating the cancer, this specific course of treatment not only results in significantly lower rates of recurrence, but as such also lowers costs to Medicare.

In the recently released 2014 hospital outpatient prospective payment system final rule, however, CMS inaccurately subjected the drug needed for this procedure to a “packaging payment” policy. Such a move virtually eliminates all reimbursement for the drug and, as a result, makes offering this service financially unfeasible for physicians and hospitals.

### **Description of Amendment**

This amendment would correct the classification CMS made in the 2014 hospital outpatient rule and ensure the drugs associated with this procedure are properly reimbursed and patients are able to access this clinically superior treatment option.

## **Menendez-Nelson Amendment #5 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Provide Hospitals in Rico the Opportunity to Qualify for the EHR Meaningful Use Program

### **Background**

The HITECH Act, signed into law in 2009, authorizes bonus payments under Medicare and Medicaid for eligible doctors and hospitals that become “meaningful users” of certified EHR systems. Unfortunately, the HITECH Act does not allow hospitals in Puerto Rico to participate in the Medicare incentive program. This exclusion appears to have been a drafting error, since the bill allows these hospitals to participate in the Medicaid program and physicians to participate in both the Medicare and Medicaid programs.

### **Description of Amendment**

This amendment would amend the HITECH Act to treat Puerto Rico hospitals like hospitals in the States, making them eligible for Medicare bonus payments if they become meaningful users of EHRs and subjecting them to penalties (in the form of reduced Medicare reimbursement rates) if they fail to meet these standards.

This amendment was introduced as a stand-alone bill by Sens. Menendez and Rubio, titled the Puerto Rico Hospital HITECH Amendments Act of 2013 (S. 636).

## **Menendez Amendment #6 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

The Urban Medicare Dependent Hospital Preservation Act

### **Background**

Just like hospitals located in rural areas, there are urban hospitals that serve high proportions of Medicare patients. However, unlike hospitals in rural areas, those in urban areas are ineligible for add-on payments to help cover the costs associated with treating this Medicare heavy population.

Recognizing the impact facing hospitals with a high percentage of patients on Medicare, the Chairman's Mark makes the rural Medicare dependent program permanent. Similarly situated urban hospitals deserve the same recognition.

### **Description of Amendment**

This amendment provides equity and parity to the Medicare Dependent Hospital policy. Specifically, the amendment establishes a specific add-on payment available to urban Medicare-dependent hospitals. This provision requires that the criteria required for a hospital to qualify for the rural MDH program be met (e.g. have no less than 60 percent of its discharges or inpatient days covered by Medicare), except that the hospital must be located in an urban area.

This amendment is budget neutral and would provide such urban Medicare-dependent hospitals with an add-on payment equal to 50 percent of the difference of the hospital's PPS payment and a hospital-specific rate based on the hospital's costs. Under the mark, similarly situated rural hospitals are entitled to a payment of 62.5 percent.

## **Menendez-Brown Amendment #7 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Improve the Calculation of the Medicare Rural Floor

### **Background**

The Balanced Budget Act of 1997 established what's known as the "rural floor" for Medicare's hospital wage reimbursements. This policy made it so that urban hospitals in a state would receive at least the same Medicare wage payment as hospitals in the state's rural areas. The payments made to hospitals under this policy are budget neutral and taken from a national funding pool, as are all other Medicare hospital payments. Recent hospital reclassifications have led to some unintended consequences that resulted in abnormally high – and completely unjustified – payments to one particular state.

### **Description of Amendment**

To correct for the unfair and unjustified payments that resulted from a single hospital reclassification, this amendment provides CMS with instructions on how to calculate the rural floor in instances where every area wage index area within a state is below the rural floor. This amendment will ensure that the rural floor policy cannot be manipulated to generate excessively high payments to all hospitals within a state and return to the rural floor policy's original intended outcome.

## **Menendez Amendment #8 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To Provide Equity and Fairness the Medicare Rural-Only Provisions

### **Description of Amendment**

This amendment will ensure that no taxpayer dollars or federal revenues that have originated from a state that does not include geographically rural hospitals or hospitals reclassified as being rural may be used to pay for Medicare services in states where such hospitals are located.

## **Menendez-Brown Amendment #9 to the SGR Repeal and Beneficiary Access Improvement Act**

### **Short Title**

To make the Family-To-Family Health Information Centers and the Maternal, Infant and Early Childhood Visitation program permanent.

### **Background**

The Family-to-Family Health Information Centers (F2Fs) provide grants to family-staffed organizations that provide health care information and resources to families of children with special health care needs.

The Chairman's Mark provides a 5-year reauthorization of the F2F program (FY14-FY18) at \$6 million a year. Additionally the Chairman's Mark would also allow US territories to be eligible for funding.

The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program facilitates collaboration and partnership at the federal, state, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Statute requires that at least 75 percent of grant funds be spent on programs to implement evidence-based home visiting models, while up to 25 percent may be spent on promising approaches that must be rigorously evaluated.

The Chairman's Mark does not provide for an extension of the MIECHV program, which is currently funded at \$400 million a year.

### **Description of Amendment**

This amendment provides that both the F2F and the MIECHV programs are made permanent. Funding for the F2F will be at the Chairman's Mark level of \$6 million per year and funding and the MIECHV will remain at the current FY14 funding level of \$400 million a year.



**Senator Carper-Bennet-Enzi-Isakson-Thune- Nelson Amendment #1** (to the bill to repeal the sustainable growth rate system and to consider health care extenders)

**Short Title:** Preventing and Reducing Improper Medicare and Medicaid Expenditures (PRIME)

**Description of Amendment:**

The amendment establishes a series of requirements to increase or enhance Medicare and Medicaid program integrity efforts, in order to curb waste and fraud. The amendment's provisions are the same as the *"Preventing and Reducing Improper Medicare and Medicaid Expenditures Act"* (or *"PRIME Act"* - S.1123), and are based on Government Accountability Office, Health and Human Services Inspector General, and other expert and stakeholder findings and recommendations. The bill does not make changes to benefits or coverage for beneficiaries, or change medical service pricing, but will help to maintain the solvency of the Medicare Trust Fund and help to moderate the growth in Medicaid expenditures.

To implement the provisions, the Secretary would be authorized to transfer funds as necessary to CMS from the Hospital Insurance (HI) and the Supplementary Medical Insurance (SMI) Trust Funds in a proportion to be determined by the Secretary. These funds would be available until expended.

The provisions are:

Sec. 101 Requiring Valid Prescriber National Provider Identifiers on Pharmacy Claims.

- Require that National Prescriber Identifiers be adopted by Centers for Medicare & Medicaid Services (CMS) as the only allowed prescriber identifier for the Medicare prescription drug program.
- Require that Prescription Drug Plan (PDP) sponsors obtain valid prescriber identifiers on all pharmacy claims under Medicare Part D, and require that the identifiers be validated.

Sec. 102 Reforming How CMS Tracks and Corrects the Vulnerabilities Identified by Recovery Audit Contractors.

- The Department of Health and Human Services (HHS) shall address overpayment vulnerabilities identified by Recovery Audit Contractors (RACs) in a timely manner, by establishing a process for tracking the effectiveness of changes made to payment policies and procedures that address the vulnerabilities identified by RACs.
- As part of previously established reporting requirements to the Congress, the HHS Secretary shall annually report on the types and financial cost of improper payment vulnerabilities

identified by RACs, how the Secretary is addressing such improper payment vulnerabilities, and an assessment of the effectiveness of changes made to payment policies and procedures. HHS shall ensure that each report does not include information that would be sensitive or otherwise negatively impact program integrity.

- HHS may retain a portion of Medicare and Medicaid recoveries to identify, recover and prevent improper payments and fraud, and for provider education. Such allocation will follow the federal-wide *Improper Payments Elimination and Recovery Act of 2010*, and also include additional funds from the recoveries for the HHS Office of Inspector General (OIG). This change will not affect the rules as to whether a recovery is made, or the level of recovery from a provider, merely the allocation of any recovery.

#### Sec. 103 Improving Senior Medicare Patrol (SMP) and Fraud Reporting Rewards.

- HHS shall develop a plan to encourage greater participation by individuals to report fraud and abuse in the Medicare program. The plan shall include recommendations for ways to enhance rewards for individuals reporting under the incentive or reward program, and extends the program to include Medicaid. The plan shall also include an improved SMP public awareness and education campaign to encourage participation.
- The plan shall be provided to Congress not later than 180 days after the date of enactment.

#### Sec. 104 Strengthening Medicaid Program Integrity Through Flexibility.

- Allow program integrity funds within CMS to be spent for hiring federal staff, whereas current law restricts some program integrity funding only through contracting. This change would allow CMS to develop more in-house program integrity expertise, and avoid losing expertise when a contract is changed.

#### Sec. 105 Establishing Medicare Administrative Contractor (MAC) Error Reduction Incentives.

- To reduce payment errors, HHS shall establish a plan to provide incentives for MACs and applicable fiscal intermediaries and carriers to reduce their improper payment error rates. The plan may include a sliding scale of bonus payments and additional incentives for MACs that reduce their error rates to certain benchmark levels and may include substantial reduction in payments under award fee contracts, for MACs that reach certain error thresholds.

#### Sec. 106 Strengthening Penalties for the Illegal Distribution of a Medicare, Medicaid, or Childrens Health Insurance Program (CHIP) Beneficiary Identification or Billing Privileges.

- Any person who knowingly, and with the intent to defraud, purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a Medicare, Medicaid, or CHIP beneficiary identification number or billing privileges under Medicare, Medicaid, or

CHIP shall be imprisoned for not more than 10 years or fined not more than \$500,000 (\$1,000,000 in the case of a corporation), or both.

Sec. 107 Access to National Directory of New Hires.

- HHS shall grant access to National Database of New Hires to CMS and the HHS OIG (under current law this database, which is maintained by HHS, excludes access to both).

Sec. 108 Improving the Sharing of Data between the Federal Government and State Medicaid Programs.

- Requires HHS to establish a plan to encourage and facilitate the inclusion of States in the Medicare and Medicaid Data Match Program and revises the Medicare and Medicaid Data Match Program to improve the program by furthering the design, development, installation, or enhancement of an automated data system to collect, integrate, and access data for program integrity, oversight, and administration purposes.
- Requires HHS to develop and implement a plan that allows each State agency access to relevant data on improper payments for health care items or services provided to dual eligible individuals.

Sec. 109 Improving Claims Processing and Detection of Fraud within the Medicaid and CHIP Programs.

- HHS shall require that for payment to be made, each claim under Medicaid and CHIP include a valid beneficiary identification number of an individual who is eligible to receive benefits.

**Carper-Toomey-Bennet Amendment #2** (to the Chairman's Mark to allow Programs of All Inclusive Care for the Elderly (PACE) to become more efficient and innovative by participating in Centers for Medicare and Medicaid Innovation (CMMI) demonstration programs)

Short Title:

Waiver Authority for Programs of All Inclusive Care for the Elderly (PACE) to participate in Centers for Medicare and Medicaid Innovation Center programs.

Description:

Current Law - Under current law, CMS does not have the authority to waive eligibility for the Programs of All Inclusive Care for the Elderly (PACE), nor can PACE participate in demonstration programs to improve health care services and increase program efficiency under Section 1115 Research & Demonstration Projects and the Center for Medicare and Medicaid Innovation (CMMI).

Amendment - The amendment allows the Programs of All Inclusive Care for the Elderly (PACE) to participate in demonstration programs under Section 1115 Research & Demonstration Projects and the Center for Medicare and Medicaid Innovation (CMMI). The waivers would permit CMS or CMMI to waive section 1934, except 1934(b)(1)(A) and 1934(c)(5).

The Secretary is also encouraged to provide, in a budget neutral manner, increased operational flexibility to support PACE programs' ability to improve and innovate, and to reduce technical and administrative barriers that have hindered enrollment in PACE.

This amendment would allow CMS and the Innovation Center to test and improve the PACE program's ability to reduce hospitalizations and emergency room use, manage chronic illness, and improve functioning and quality of life.

**Carper-Isakson-Rockefeller-Wyden-Cardin Amendment #3** (to the Chairman's Mark to develop quality measures to ensure the transfer of existing patient care information and preferences)

Short Title:

Quality Measurement to Encourage Health Care Providers' Transfer of Existing Patient Care Preferences

Description:

Current Law - Under current law, hospitals, nursing homes, and home health agencies frequently fail to transfer notice of existing patient health care information and preferences when patients are discharged from the hospital or move into a new care setting. As a result, patients may receive inadequate or inappropriate services that do not follow the patients' own preferences and decisions.

Amendment - The amendment would direct the HHS Secretary to contract with measure developers to create, and submit for endorsement by a consensus-based entity, a Medicare quality measure for hospitals, nursing homes, and home health agencies to ensure that the notice of documentation related to patient health information and care preferences are transferred with patients as they move to other care settings or return home. These Medicare quality measures would be reported by hospitals, nursing homes, and home health agencies as part of existing quality reporting programs.

**Senator Carper-Toomey-Brown Amendment #4** (to the bill to repeal the sustainable growth rate system and to consider health care extenders).

**Short Title:** Improvements to Medicare Procedures to Prevent Fraudulent Diversion and Medically Unnecessary or Unsafe Use of Prescription Drugs

**Description of Amendment:** This amendment requires steps by the Secretary of the Department of Health and Human Services (HHS) to curb the fraudulent diversion and abuse of prescription drugs involving Medicare beneficiaries. The amendment requires that the Secretary establish steps to identify excessive, non-medically necessary uses of prescription drugs and fraudulent behavior, implement appropriate education and controls, and ensure necessary beneficiary access to medication. The amendment would also allow appropriate beneficiary-level, anti-fraud data sharing between Medicare prescription drug plan sponsors and the Centers for Medicare & Medicaid Services to allow effective reviews and prevent further abuse.

To implement the provisions, the Secretary would be authorized to transfer funds as necessary to CMS from the Hospital Insurance (HI) and the Supplementary Medical Insurance (SMI) Trust Funds in a proportion to be determined by the Secretary. These funds would be available until expended.

The Social Security Act is amended to include the following requirements:

- 1) **DATA SHARING** - The HHS Secretary shall establish rules and procedures that require Medicare Part D prescription drug plans and Medicare Advantage prescription drug plans (MA-PD) to share anti-waste and fraud data with the Centers for Medicare & Medicaid Services (CMS), as well as CMS appropriately sharing anti-waste and fraud data with the prescription drug plans, for the purpose of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and show indications of fraudulent, medically unnecessary, or unsafe use.
- 2) **PRIVACY ISSUES** - The HHS Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, related to the sharing of data by stand-alone Prescription Drug Plan sponsors and MA organizations for the purposes of preventing fraud and abuse under this Program. The Secretary shall clarify that the sharing of this information shall be considered to be “protected health information.”
- 3) **ESTABLISHMENT OF PROGRAM FOR MA-PD PLANS** - Within one year of passage, the HHS Secretary shall implement a beneficiary protection program for MA-PD plans through a notice and comment rulemaking process to prevent fraudulent diversion and medically unnecessary or unsafe use of prescription drugs under this part. As part of the plan, the HHS Secretary shall include requirement for each MA-PD plan to:

(A) utilize clinical and statistical evidence, outside complaints, referrals, or other appropriate sources to identify patterns of prescription drug utilization for enrollees of the plan that are outside normal patterns and show indications of fraudulent, medically unnecessary or unsafe use and communicate this information as appropriate to the Secretary;

(B) Implement appropriate controls to address prescription drug misuse, abuse, and diversion that begin with education, outreach, and counseling, and, as a last resort, utilize pharmacy or provider assignment programs;

(C) Have a mechanism to promptly inform the Secretary and other MA organizations (under procedures established by the Secretary) about controls imposed (or any decision to impose controls) with respect to an enrollee.

(D) Include strong protections for the medical needs and rights of beneficiaries, including robust access to appropriate medications.

4) CONSULTATION WITH STAKEHOLDERS – Before implementation of the beneficiary protection program for MA-PD plans, the Secretary shall consult with stakeholders including MA organizations offering MA–PD plans, State Medicaid program officials and Medicaid managed care plans with experience in implementing beneficiary protection programs for Medicaid beneficiaries, beneficiary advocacy organizations, state and national physicians’ groups, retail and community pharmacy groups, pharmaceutical manufacturers, prescription benefit managers, and others as the Secretary determines appropriate.

5) PROGRAM OVERSIGHT.—The Secretary shall exercise appropriate oversight over the beneficiary protection program for MA-PD plans to ensure—

(A) Consistent and equitable treatment of enrollees by MA organizations offering prescription drug plans;

(B) Reasonable access by enrollees to all covered drugs, including emergency access;

(C) Reasonable enrollee accommodation regarding any controls imposed; and

(D) Establishment of a robust appeals and grievance process to address and resolve enrollee complaints and problems, and ensure appropriate access to medications.

REPORTS TO CONGRESS - Beginning 18 months after the Program’s enactment, and for each of the succeeding 3 years, the Secretary shall submit to Congress a report on the Program.

**Carper-Enzi Amendment #5** (to the Chairman's Mark to request a GAO report on medical malpractice reform)

Short Title:

GAO report to evaluate reforms to reduce medical liability costs, to improve health care quality, and to increase patient safety

Description:

This amendment would require a GAO report, due two years following the enactment of the underlying bill, to evaluate reforms to reduce medical liability costs, to improve health care quality, and to increase patient safety. The report should address the following questions:

1. Describe examples of medical liability reform programs instituted in selected states or entities within those states, including implementation issues, goals and results.
  - a. What have been the challenges, if any, in implementing the programs?
  - b. What performance goals or measures have been used to assess the programs and what are reported results?
  
2. Describe what is known about the effect on patient safety and satisfaction, health care quality, or medical liability by public and private reporting systems that receive information related to medical errors or near-misses.
  - a. What features of patient safety reporting systems facilitate or inhibit reporting of medical errors or near-misses, including both public reporting systems (such as, the National Practitioner Data Bank and selected state-sponsored systems) and private reporting systems, including self-reporting systems and Patient Safety Organizations?
  - b. How can Patient Safety Organizations be restructured to increase provider reporting and increase their impact on quality and safety of patient care?
  - c. What impacts, if any, have such reporting systems had on improving patient safety?
  - d. What is known about the ability for patient safety reporting systems to affect medical liability claims?



**Senator Carper Amendment #6** (to the bill to repeal the sustainable growth rate system and to consider health care extenders)

**Short Title:** Improving Accountability, Transparency, and Effectiveness of Oversight and Audit Activities under the Medicare Program

**Description of Amendment:** The amendment would add requirements to Title XVIII of the Social Security Act for the HHS Secretary to establish and implement a plan to ensure strong accountability, transparency, and effectiveness of oversight and audit activities under the Medicare program. The plan shall apply to all Medicare claims oversight and audit activities and contractors (such as Recovery Audit Contractors), and including appeals adjudicated by administrative law judges, that are focused on identifying, preventing, and recovering improper payments. The plan shall not apply to any oversight or audit activities related to the investigation or prosecution of fraud or other law enforcement activity under this title.

To implement the provisions, the Secretary would be authorized to transfer funds as necessary to CMS from the Hospital Insurance (HI) and the Supplementary Medical Insurance (SMI) Trust Funds in a proportion to be determined by the Secretary. These funds would be available until expended.

The plan will:

- 1) Establish a process to address providers of services and suppliers' questions on payment, coverage policy, and issues related to claim status across contractors, including claim denials. The Secretary may establish a new or make use of an existing Medicare ombudsman office or process;
- 2) Improve transparency of denied claims by the use of a single, secure Internet-based system that allows providers of services and suppliers to determine the status of Medicare claims under review by any oversight and audit contractor, or by an administrative law judge;
- 3) Ensure that all Medicare claims audit issues conform to the Centers for Medicare & Medicaid Services policy; and that the providers of Medicare services and suppliers receive notification within a specific number of days of claim denial regarding the result of each audit or review conducted with respect to the claim, or the appeal of a denied claim; and
- 4) Ensure that an oversight and audit contractor does not review a claim for payment under this title that is currently being reviewed or was previously reviewed by another oversight and audit contractor.

**Carper-Grassley Amendment #7** (to the Chairman’s Mark to require certification and endorsement of Medicare quality metrics related to medication adherence and to require Medicare Part D plans to increase patient medication education and adherence)

Short Title:

Increasing Patient Medication Education and Adherence

Description:

More than 50 percent of patients with chronic diseases in the United States do not take medications as prescribed. Low rates of medication adherence result in higher health care costs, reduced effectiveness of health care treatments and regimens, negative health effects for patients, and tens of thousands of deaths on an annual basis. In 2012 alone, health care costs of more than \$200 billion were caused by improper use of medicines. Improving medication adherence could save as much as \$290 billion each year while also improving patient health outcomes.

Amendment – By no later than two years after passage of the underlying bill, the Centers for Medicare & Medicaid Services (CMS), in coordination with other agencies of the Department of Health and Human Services, shall:

- contract with private entities and stakeholder groups to develop, and submit for endorsement by a consensus-based entity, comprehensive baseline measures of medication adherence for use by accountable care organizations, patient-centered medical homes, Medicare Part D plans, pharmacists, and other health care programs and providers as specified by the Secretary;
- test the effectiveness of specific interventions, and where possible, programs by Medicare Part D plans and in conjunction with pharmacists, to improve medication adherence and increase medication synchronization through the CMS Innovation Center; and
- provide to Medicare Part D plan enrollees, their designated representatives, pharmacists, and health care providers every three months, a list of all covered part D drugs provided to the enrollee under the plan during the preceding three months.

**Cardin Amendment #1 to the Chairman's Mark (The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013)**

**Short Title: Eliminating Beneficiary Coinsurance for New Chronic Care Management Codes to encourage participation**

Background: The Chairman's Mark directs the Secretary to establish one or more Health Care Common Procedure Coding System (HCPCS) codes for chronic care management services for individuals with chronic care needs. These codes will take effect for services furnished on or after January 1, 2015.

CMS has found that the 14% % of Medicare beneficiaries with six or more chronic conditions account for 46% of total Medicare spending.\* These patients already pay higher out-of-pocket costs due to more frequent hospitalizations and physicians' visits. Overall health care costs and beneficiaries' out-of-pocket expenditures would be lowered if these patients are incentivized to participate in programs that will lead to more cost-effective management of their conditions.

Description of the Amendment: The amendment would eliminate beneficiary coinsurance for these codes to encourage beneficiary participation.

\*Source: CMS, Chronic Conditions Among Medicare Beneficiaries, Chartbook: 2012 Edition

**Cardin-Bennet-Brown Amendment #2 to the Chairman's Mark (The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013)**

**Short Title: Targeted Outreach to Rural and Minority Communities for Participation in Care Management for Individuals with Chronic Care Needs**

Background: The Chairman's Mark emphasizes the role that care coordination and population health management can play in improving health status and transforming the Medicare program. However, because of limited resources, underserved communities may be less likely to have access to care through innovative delivery models like ACOs. For chronically ill beneficiaries in these areas, participation in chronic care management services will allow them to benefit from coordinated care necessary to address their unique needs.

Description of the Amendment: The amendment would require the Secretary to conduct an education and outreach campaign to inform providers and seniors of the benefits of chronic care coordination and encourage participation by seniors with multiple chronic conditions. The Secretary shall work through the HHS Office of Rural Health Policy and the CMS Office of Minority Health to encourage participation by underserved rural populations and racial and ethnic minority populations. The Secretary shall report to Congress by December 31, 2017 on the representation of beneficiaries living in rural areas and of racial and ethnic minority populations in the Chronic Care Management program, identify any barriers to participation, and make recommendations for increasing participation.

**Cardin Amendment #3 to the Chairman's Mark (The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013)**

**Short Title: Blocking further implementation of the Multiple Procedure Payment Reduction (MPPR) to the professional component of Advanced Diagnostic Imaging Services**

Background: The professional component represents reimbursement from Medicare for the radiologists' interpretation of an image for either the presence of disease, such as cancer, or patient trauma. CMS initially implemented this arbitrary reimbursement reduction through the 2012 Medicare Physician Fee Schedule Final Rule without any in-depth, publically available data analyses in justification of the cut. The Agency incorrectly argues that when radiologists interpret multiple images from the same patient, during the same session, on the same day, there are ample "efficiencies," or overlapping work, to justify a corresponding reduction in reimbursement.

But radiologists spend an equal amount of time, energy, and expertise interpreting images regardless of the date of service, equipment being used, or section of the body that is under examination. In June 2011 an expert panel of radiologists published a peer-reviewed study in the *Journal of American College of Radiology* (JACR) which found that professional component efficiencies vary by modality and are ultimately no greater than 3 to 5%.

Rectifying the unintended consequences of CMS's PC MPPR policy will ensure that radiologists can continue to provide patients with important, life-saving advanced diagnostic imaging services.

CMS reports that they completed their own analysis in the 2012 MPFS Final Rule and even provide ranges of data related to the total amount of efficiencies in the PC. Yet, the agency has been unwilling to fully disclose the "line-by-line" data in a format that can be reviewed by Congress. Without the release of a line-by-line data analysis, Congress is unable to determine whether the reduction is warranted.

Description of the Amendment: This amendment is budget neutral. It would stop CMS from further implementing the 25% multiple procedure payment reduction assessed to the professional component of radiologists' services. It would also require CMS to disclose within 60 days of enactment, any relevant empirical analyses used by CMS to justify the imposition of the professional component MPPR in 2012. The amendment closely mirrors language of S. 623, the Diagnostic Imaging Services Access Protection Act, which has 20 bipartisan cosponsors.

**Cardin-Portman Amendment #4 to the Chairman’s Mark (The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013)**

**Short Title: To encourage the use of efficient dispensing techniques for long-term care pharmacies**

Background: In 2010, Congress mandated that HHS require prescription drug plan sponsors (PDPs) to “utilize specific, uniform dispensing techniques...such as weekly, daily, or automated dose dispensing, when dispensing covered Part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.” CBO scored this provision as saving \$5.7 billion over 10 years.

The final rule issued by CMS in 2011 requires 14-day or less dispensing, but it does not specify the professional fee methodology to be paid by PDP sponsors to long-term-care pharmacies (LTCs).

Starting in January 2013, Part D plan sponsors began to use payment structures, such as prorated daily dispensing fees, that actually encourage dispensing of greater quantities even though that practice leads to wasted medications and negates the intent of the short-cycle dispensing policy.

Example

PDP Reimbursement Methodology to LTC Pharmacies			
# of Days Supplied	2012 \$4.50 per month per script	2013 \$0.16 x # of days supplied	Change in Reimbursement (2013 – 2012)
2	\$4.50	\$0.32	-\$4.18
14	\$4.50	\$2.24	-\$2.26
30	\$4.50	\$4.80	+\$0.30

Description of the Amendment: The amendment would require PDP’s professional fees for the dispensing of outpatient prescription drugs in LTC facilities to be a flat fee, linked to the professional services required under the law, and designed to foster efficiencies and reduce wasteful dispensing of drugs, consistent with Congressional intent.

**Cardin-Grassley Amendment #5 to the Chairman's Mark (The SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013)**

**Short Title: Community-Based Institutional Special Needs Plan Demonstration Program**

Background: Under current policy, Medicare does not cover the community-Based long-term services and supports (LTSS) that play an essential role in keeping individuals out of institutional settings. Without LTSS, these individuals frequently experience negative health outcomes and lose their ability to live independently.

The proposed Community-Based Institutional Special Needs Plan (CBI-SNP) demonstration would address the urgent need to prevent the institutionalization that frequently leads to "spend-down" for low-income Medicare beneficiaries. It would target Medicare beneficiaries whose health status and functional limitations put them at risk of nursing facility placement, and whose financial status places them on the verge of Medicaid eligibility. The proposed demonstration would match LTSS services with an advanced clinical model of care to prevent or delay nursing home placement and Medicaid "spend-down," and thereby lead to improved quality of life for beneficiaries and lower costs for government.

Validating a care model that delays Medicaid "spend-down" and reduces the number of Medicare beneficiaries who become dually-eligible would have a powerful impact. State and the federal government share the cost of the Medicaid long term care burden, and the strain state and federal budgets experience will only increase as the Baby Boom generation ages.

The proposed goals of the demonstration would include: (1) reducing Medicaid long term care (LTC) costs; (2) reducing Medicare acute care costs; (3) reducing Medicare LTC costs for beneficiaries, and thereby reducing the number who spend down to Medicaid eligibility; (4) generating evidence to support an alternative payment methodology whereby states and the federal government jointly finance a package of LTSS to Medicare-only beneficiaries and share in the savings.

Program participants would be drawn from the following areas: Institutional special needs plans (I-SNPs) that have the capability to integrate LTSS with Medicare benefits; other Medicare advantage plans that could develop the expertise to effectively provide customized LTSS benefits in the near future; Medicaid managed care plans that have relevant experience and could expand LTSS to the targeted population.

Description of the Amendment: This amendment would establish 0a Community-Based Institutional Special Needs Plan (CBI-SNP) demonstration program, consisting of not more than five plans, aimed at preventing or delaying institutionalization and "spend-down" among the at-risk Medicare population. Medicare beneficiaries who are below 150% of the federal poverty level and who are unable to perform two or more activities of daily living would become eligible to receive community-based long-term services and supports that address their health needs and promote independent living. The Center for Medicare and Medicaid Innovation (CMMI) would fund the 3-year demonstration. An independent third party would conduct an evaluation to determine if the program has reduced hospitalizations, re-hospitalizations and nursing facility stays, and prevented or delayed participating beneficiaries from spending down their assets and becoming eligible for Medicaid. Should the Secretary extend the initial 3-year period, funding

for the beneficiary population shall not exceed the amount HHS would have paid had the demonstration had not been implemented.



**Brown Amendment # 1** (to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013). Offered with Sens. Rockefeller and Stabenow

**Purpose:** To Extend the Health Coverage Tax Credit for Displaced Workers

**Short Title:** Health Care Coverage for Displaced Workers Extension

**Description of Amendment:** This amendment extends the Health Coverage Tax Credit (HCTC) for displaced workers, which is set to expire on December 31, 2013, for a period of one year. The HCTC helps retirees who lost their health care coverage when the companies for which they worked either entered into bankruptcy or moved operations overseas. This extension is intended to provide time for displaced workers who have used the tax credit to make health insurance affordable to learn more about their options, and transition over to other insurance plans of their choosing.

**Brown Amendment # 2** (to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013). Offered with Sen. Stabenow.

**Purpose:** To count a period of receipt of outpatient observation services in a hospital toward satisfying the 3-day inpatient hospital requirement for coverage of skilled nursing facility (SNF) services under Medicare.

**Short Title:** Improving Access to Medicare Coverage

**Description of Amendment:** This amendment would provide beneficiaries who need SNF care after their hospitalization a pathway to receive it as a covered Medicare benefit. Under current law, Medicare will only cover SNF benefits if the patient had three consecutive days of hospitalization as an inpatient, not counting the day of discharge. However, hospitals are increasingly caring for Medicare beneficiaries on “outpatient observation status” instead of admitting them as inpatients—a billing technicality. Because of this technicality, some patients are enduring lengthier hospital stays in observation status and may unknowingly be treated under outpatient observation status for the entirety of their hospital visit. This creates two groups of beneficiaries who need SNF care after their hospitalization – those who are admitted and treated and therefore covered under Medicare, and those who are kept under observation status and treated and therefore ineligible for Medicare coverage. This amendment would correct the technicality and allow all beneficiaries who were hospitalized at least 3 days and then entering a SNF after hospitalization to receive it as a covered Medicare benefit.

**Brown Amendment # 3** (to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013). Offered with Sens. Rockefeller and Stabenow

**Purpose:** To Extend the Medicaid Parity with Medicare for Primary Care Reimbursement for an Additional Year

**Short Title:** Medicaid Parity with Medicare for Primary Care Reimbursement

**Description of Amendment:** Continued support for primary care practice remains critical in the effort to increase access to care and to focus that care on health, wellness, and prevention rather than just on “sick care”. This amendment extends the current two-year Medicaid payment bump for primary care, which runs for 2013 and 2014, continuing the parity with Medicare payments in 2015. Payment for primary care services in Medicaid (including managed care) for 2015 will be paid at no less than 100 percent of the Medicare Part B physician rates for the same services. For the additional amount the state spends to fill that gap, the FMAP will be 100%.

Primary care services are defined as evaluation and management (E&M codes) and vaccination administration, and must be delivered by a provider with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine.

## **Bennet-Cornyn Amendment #1 to The SGR Repeal and Medicare Beneficiary**

### **Access Improvement Act of 2013**

**Short title/Purpose:** The purpose of this amendment is to incentivize states to achieve reductions in future health care cost growth while improving quality.

**Description of the Amendment:** The Secretary shall establish a State Innovation and Savings Initiative under which the Secretary shall make shared savings payments to States that demonstrate an ability to reduce future increases in health care costs at the State level.

This Initiative would allow States to apply to the Secretary of Health and Human Services, in coordination with the Secretary of the Treasury, to receive a shared savings payment if they are able to reduce future increases in health care costs through effective collaborations with key stakeholders. Shared savings payments to States would be generated from reductions in health care spending through Medicare, Medicaid, tax expenditures, and budgeted savings. These payments would be made on a sliding scale and increase as States reach a higher level of total savings. In making determinations, the Secretary, in coordination with the Secretary of the Treasury, shall not take into consideration any decrease in expenditures or savings that may have occurred as a result of the implementation of policies that result in cost-shifting between State and Federal governments, one or more public programs, or the public and private sectors.

**Bennet-Crapo Amendment #2 to The SGR Repeal and Medicare Beneficiary  
Access Improvement Act of 2013**

**Short title/Purpose:** To establish a long-term global budget for total Federal health care spending.

**Description of the Amendment:** This amendment would create an expedited process to address instances in which the growth of our Federal health care programs exceeds our nation's Gross Domestic Product (GDP) + 1%. Specifically, in a year in which the CBO concludes that the growth of our health care programs is increasing faster than this target, the amendment would set up a fast-track process for Congress to find savings to bring our Federal health care spending in line with GDP + 1% and protect the long-term solvency of our nation's health care programs.

**Bennet-Cornyn #3 Amendment to The SGR Repeal and Medicare Beneficiary  
Access Improvement Act of 2013**

**Short title/Purpose:** To improve the transparency and predictability of Medicare local coverage decisions for molecular pathology services.

**Description of the Amendment:** This amendment would require that CMS or any Medicare Administrative Contractor who provides coverage making decisions for molecular pathology services (including multianalyte assays with algorithmic analyses and genomic sequencing analyses) provide written guidance to clinical laboratories as to the criteria and processes used to approve coverage for novel molecular pathology services. This guidance shall include timelines and, if the Contractor the uses of subject matter expert advisors outside the Contractor Advisory Committee process, the guidance shall explain the procedures and criteria related to the use of such experts.

## **Bennet-Toomey #4 Amendment to The SGR Repeal and Medicare Beneficiary**

### **Access Improvement Act of 2013**

**Short Title/Purpose:** To Require the Secretary of HHS to Conduct a Pilot Program to Improve Care and Lower Costs for the Highest Cost Medicare Beneficiaries

**Description of Amendment:** The Secretary of Health and Human Services will be required to conduct a three-year pilot program to demonstrably improve patient care and achieve cost savings for the highest cost five percent of Medicare fee-for-service beneficiaries. No later than January 1, 2015, Secretary will establish a specialized capitated pilot program in three regions into which certain high-cost Medicare beneficiaries shall be enrolled, that provides person-centered, comprehensive and integrated care management and services with a network of “best-in-class” providers, including Centers of Excellence and specialized medical centers. Any Medicare beneficiary enrolled in this program shall have a personalized care plan developed with an assigned nurse coordinator and access to a coordinated care team. Special consideration of geographic access to adequate providers shall be taken into account for Medicare beneficiaries living in rural areas. The Secretary shall implement this program through a competitive process, and award or select one participating health insurance plan per geographic service area.

Under this program eligible health insurance plans meeting criteria specified by the Secretary would receive a risk-adjusted capitation payment from CMS for all Medicare-covered services and would enter into collaborative risk-sharing arrangements with its core group of providers. The capitation payment shall be based on historical and projected costs for comparable Medicare beneficiaries and would guarantee savings to the federal government by setting the capitation rate at 95 percent of the projected baseline costs for the enrolled population, with appropriate geographic and risk adjustment. Participating plans would be required to collect and report on a set of quality and outcomes measures. The Secretary would have the authority to expand the program nationwide if results of the three-year pilot program meet specified quality improvement and cost savings goals.

## **Bennet-Thune #5 Amendment to The SGR Repeal and Medicare Beneficiary**

### **Access Improvement Act of 2013**

**Short title/purpose:** To allow Medicare qualified entities to use secure and appropriate methods of technology to help providers to improve quality and transparency in healthcare delivery.

**Description of Amendment:** The Chairman's Mark expands the current definition of a Qualified Entity, which are organizations deemed by the Centers for Medicare and Medicaid Services to be qualified to access Medicare claims data for the purposes of evaluating provider and supplier performances and to make those evaluations available to the public. The Chairman's Mark also allows a qualified entity that provides or sells access to its CMS data combined with its other data to a defined group of providers through a data enclave.

This amendment would expand this concept to allow a qualified entity to provide data, which could include average, median, or standardized pricing, or analysis of its data to authorized users using other appropriate methods, such as secure transfer of the data or analysis, as determined acceptable by the Secretary. If another appropriate method is used, the Secretary could enforce additional protections of the data between qualified entities and its users, such as a data use agreement or monetary penalties.



## **Bennet-Cornyn Amendment #6 to The SGR Repeal and Medicare Beneficiary**

### **Access Improvement Act of 2013**

**Short title/Purpose:** To better inform taxpayers about their individual Medicare contributions and benefits by including information in a yearly statement they already receive about Social Security.

**Description of the Amendment:** This amendment seeks to amend title XI of the Social Security Act to provide for the annual mailing of statements of Medicare beneficiary part A contributions and benefits in coordination with the annual mailing of Social Security account statements.

For individuals who receive an annual Social Security statement through the mail or online, this amendment would include annual Medicare Part A information as well, which would be comprised of the following: a summary of Medicare's benefits and options, an individual's total Hospital Insurance (HI) contributions, actuarial estimate of expected contributions during the individual's lifetime, an individual's total received benefits, and an actuarial estimate of actual and/or expected benefits during individual's lifetime.

## **Casey-Rockefeller-Brown-Wyden Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Performance Bonus Payment to Offset Additional Medicaid and CHIP Enrollment Costs Resulting from Enrollment and Retention Efforts

### **Purpose:**

To amend Title XXI of the Social Security Act to extend the existing performance bonus payments under CHIP and Medicaid through CHIP's current authorization (through FY 2015).

### **Background:**

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) established performance bonuses, giving states an incentive to support enrollment and retention of eligible children in Medicaid and CHIP and helping to defray the costs associated with increasing enrollment of the lowest income children. In FY 2012, 23 states received performance bonuses.

### **Description:**

This amendment is a straight reauthorization of the existing performance bonus program, established by Sec. 304 of CHIPRA, through FY 2015. This program expired on September 30, 2013. The performance bonuses reward states for making it easier for children to enroll in Medicaid and CHIP, and for successfully increasing enrollment of eligible children.

States must meet 5 of the following 8 criteria:

- 12-month continuous eligibility (Allows full-year enrollment regardless of income or other changes.)
- Elimination or reduced verification of asset requirements
- No requirement for an in-person interview
- Same application and renewal forms for Medicaid and CHIP
- Automatic/administrative renewal (pre-populated form; electronic verification used to streamline renewal)
- Presumptive eligibility (allows health care providers and other entities to screen and presumptively enroll children; children have access to needed benefits while the full eligibility process is being completed)
- Express Lane Eligibility (States can use eligibility findings from other public benefit programs, such as the Supplemental Nutrition Assistance Program (SNAP) to determine eligibility for Medicaid and CHIP.)
- Premium Assistance

Additionally, states must meet statutorily-defined targets for increases in enrollment. In 2009, these were based on the average monthly number of enrolled Medicaid children in 2007, with adjustments based on Census Bureau estimates of child population growth (from 2007-2008 plus 4 percentage points and from 2008 and 2009 plus four percentage points). After 2009, the baseline was set from the prior year's number plus state child population growth plus additional percentage point increases that are lower than the 4 percentage points for FY2009: for FY2010 to FY2012, 3.5 percentage points; for FY2013 to FY2015, 3 percentage points; and FY2016 onward, 2 percentage points.

## **Casey-Rockefeller-Bennet-Brown Amendment #2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Express Lane Eligibility

### **Purpose:**

To amend Title XXI of the Social Security Act to improve the Medicaid Express Lane eligibility determinations process, to allow states additional flexibility to use Express Lane eligibility to enroll parents and other eligible adults.

### **Background:**

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) established a Medicaid state plan option for "Express Lane" eligibility (ELE) that expires on September 30, 2014. The Chairman's Mark (section 213) extends the authority for these ELE determinations until September 30, 2015.

### **Description:**

CHIPRA established express lane eligibility (ELE) to allow states to use determinations from other federal programs (such as the School Lunch program, SNAP, TANF, WIC and Head Start) to facilitate enrollment of eligible children into Medicaid and CHIP. ELE simplifies the administration and enrollment process for states.

Thus far, 12 states and the U.S. Virgin Islands have taken advantage of ELE in Medicaid or CHIP. A 2012 GAO study found that significant administrative savings are possible with ELE. ELE expires at the end of FY 2014. This amendment, in addition to the extension included in the Chairman's Mark, would give states additional flexibility to use ELE to enroll eligible parents and other newly-eligible adults in addition to children. States will benefit from additional administrative and paperwork burden reductions.

## **Casey Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** Delay of CMS CY14 HOPPS Final Rule Implementation of Skin Substitute Bundling for Advanced Therapeutic Wound Healing Products

**Description of Amendment:** This amendment provides that in 2014, for FDA-approved advanced therapeutic wound healing products, instead of implementing a new bundle/package proposal, CMS would instead continue to pay separately for such products. This amendment responds to a provision in the Final HOPPS Rule for CY2014 that would not only for the first time bundle advanced therapeutic wound healing products, but also bundle them with unlike products that have not been through the rigorous FDA premarket approval (PMA) or Biologic License Application (BLA) processes. If implemented, the new rule will devastatingly cut payment rates for these advanced therapeutic products, making their continued production unsustainable and leaving clinicians without alternatives to conventional treatments for patients with chronic wounds such as diabetic foot ulcers and venous leg ulcers. In the absence of such products, patients are more likely to suffer bone infections, hospitalizations, and amputations, leading to higher Medicare spending to support less acceptable patient outcomes. By delaying implementation of the HOPPS Rule bundle/package for one year, the amendment ensures that CMS will continue to reimburse as it has since 2001 using a methodology based on average sales price plus an add-on percentage (6% in the most recent year).

## **Grassley-Wyden Amendment #1 to the Chairman's Mark**

**Title:** Transition to Independence Medicaid Demonstration

**Purpose:** The purpose of this amendment is to increase the opportunities youth with disabilities have to transition to independent living and work in the community.

**Description of Amendment:** This amendment authorizes the Secretary to create an up to ten-state Medicaid demonstration program. The demonstration program would create a bonus pool that requires states to do the following:

- States will receive bonus payments for meeting minimum standards for Medicaid Buy-In Program;
- States will receive bonus payments for achieving a reduction in sheltered workshop and facility based day habilitation census of 25%, 50%, 75% and 100% with different bonus payments at each level;
- States will receive bonus payments for achieving increases in number of people with disabilities in integrated, individualized supported employment by 25%, 50%, 75% and 100%, with different bonus payments at each level;
- States will receive a bonus payment for establishing an inter-agency collaboration agreement between vocational rehabilitation, education department (particularly through coordination with the PROMISE grant), and the state Medicaid authority in determining payer of last resort rules and laying out seamless transition of service-provision;
- States will receive bonus payments for reducing new approvals for sheltered work;
- States will receive bonus payments for reducing funding (from both Medicaid & vocational rehabilitation) for sheltered workshops.

The demonstration would focus on disabled individuals covered under the state Medicaid program between ages 14 and 30.

## Grassley-Stabenow Amendment #2 to the Chairman's Mark

**Title:** Quality Care for Moms and Babies Amendment

**Purpose:** The purpose of this amendment is to improve the quality of health care for moms and babies.

**Description of Amendment:** This amendment will require a review of maternity care quality measures in the Medicaid and the Children's Health Insurance Program (CHIP), support the development of new measures as needed, and support the establishment and expansion of maternity care quality collaboratives.

The amendment directs the Secretary of Health and Human Services (HHS) to work with relevant stakeholders, including medical specialties, to identify gaps in quality measures endorsed under section 1890(b)(2) of the Social Security Act as applied under titles XIX and XXI of the act. It directs the Secretary to develop and publish core Maternal and Infant Care (MIC) quality measures for childbearing women and newborns under the Medicaid Quality Measurement Program Measures and the CHIP Child Health Quality Measures.

The Secretary would be required to review these measures on an ongoing basis through qualified measure development entities to identify needed additions, modifications, or eliminations. The measures would be evidence-based, utilize risk adjustment, be pilot tested, and pertain to process, experience, efficiency, and outcomes of maternity care. The amendment will also require qualified measure development entities to create eMeasures as part of the MIC quality measures for ready collection through electronic health records. A qualified measure development entity must have demonstrated expertise and capacity in the development and testing of quality measures, and include procedures for the input of a broad range of stakeholder views. The amendment would authorize to be appropriated \$16 million to carry out these new measure development activities.

The amendment would also allow the Secretary to make grants to eligible entities for the development of new State and regional maternity care quality collaboratives and the expansion of existing quality collaboratives. The collaboratives would help identify and spread the adoption of best practices and improved maternal and infant outcomes. The amendment would authorize to be appropriated \$15 million for these grants.

Entities eligible to receive these grants would include: existing quality collaboratives; entities seeking to establish maternity care quality collaboratives; state Medicaid agencies; state departments of health; health insurance issuers; and, provider organizations including associations representing health professionals and hospitals. Eligible projects will include: reducing maternal and morbidity rates; improving the appropriate use of cesarean section; and, reducing hospital readmissions, among others. Activities eligible for funding by the collaboratives would include: facilitating performance data collection and feedback reports to providers; developing protocols and checklists; developing needed infrastructure to support the collaboratives activities; providing technical assistance to providers and institutions to participate in collaboratives; and, developing the capability to access necessary data sources.

Collaboratives receiving grants would have to provide annual reports to the Secretary and must be governed by a multi-stake-holder executive committee that includes physicians, nurse practitioners, certified nurse-midwives and certified midwives, healthcare facilities and health systems, consumers, employers and other private purchasers, Medicaid programs and other public health agencies and organizations.

## **Grassley-Wyden-Carper Amendment #3 to the Chairman's Mark**

**Title:** Medicare Risk Adjustment Prize for Performance Competition

**Purpose:** The purpose of this amendment is to improve risk adjustment in Medicare by opening the creation of the adjustor to a competition.

**Description of Amendment:** This amendment would instruct CMS to undertake the following actions:

- Beginning in 2015, CMS will be required to update MA risk adjustment every four years.
- CMS will be required to select a contractor to make a proposal for risk adjustment.
- CMS will be required to conduct a Prize for Performance Competition (PPC).
- The PPC will provide two data sets to competitors: a training data set and a test data set. Data sets will include encounter, claims, drugs, labs, sociodemographic, and full 5 digit zip code. Data cannot include patient identifying information.
- Competitors will use the two data sets to construct proposals for risk adjustment.
- Prizes (\$10M, \$5M, \$2M) will go to the three proposals for risk adjustment that improve on the accuracy of the current risk adjustor the most so long as proposals improve risk adjustment by a minimum of four percent. If no proposal reaches the 4% goal, the proposal with the highest percentage receives \$1M.
- CMS will decide PPC proposal winners.
- CMS shall take into account the PPC proposals and the contracted proposal in approving a final risk adjustment policy.



## **Grassley Amendment #4 to the Chairman's Mark**

**Title:** Cost Contracts Technical Amendment

**Purpose:** The purpose of this amendment is to modify the two plan competition test to count enrollment of competing MA plans only in the service areas that the MA plans share with the Medicare cost plan.

**Description of Amendment:** This amendment modifies the two plan competition test to count enrollment of competing MA plans only in the service areas that the MA plans share with the Medicare cost plan.

**Grassley-Bennet-Toomey-Nelson-Portman-Rockefeller-Casey-Brown-Cantwell  
Amendment #5 to the Chairman's Mark**

**Title:** Coordinated Care for Medically Complex Children

**Purpose:** The purpose of this amendment is to establish under the Medicaid program and Children's Health Insurance Program (CHIP) an accountable care collaborative providing a network of services to children with medically complex conditions.

**Description of Amendment:** This amendment establishes a Medicaid Children's Care Coordination (MCCC) Program for children with complex medical conditions that will provide services through nationally designated children's hospital networks. Medically Complex Children are defined as those who are included in Clinical Risk Groups (CRG) 5b-9. The CRG methodology is a well-documented and accepted manner of classifying pediatric patients and their diagnoses nationally and can be adopted for these purposes easily.

Patients in these CRG groups have significant lifelong chronic diseases, limiting the probability of churning in and out of the network. Services provided to patients in the network under agreement with the Secretary include all services available under Title 19 and 21. Approximately 3,000,000 children in the country suffer from medically complex conditions and 2,000,000 of these children are in Medicaid, accounting for 6 percent of children enrolled in Medicaid and 40 percent of Medicaid spending on children.

Children's hospitals are seen as the anchors to the nationally designated hospital network. While anchor hospitals will provide services for network patients including physician, inpatient and outpatient care, the network will necessarily include other hospitals, physicians, and providers to ensure these children receive the needed services in the most appropriate setting possible. Key to these networks is assurance that there is an adequate network to support the specific pediatric population.

Through integrated care and risk-based reimbursement, improved patient outcomes and lower health care costs can be achieved.

## Grassley Amendment #6 to the Chairman's Mark

**Title:** Medicare Part D and Transparency of Payment Methodology

**Purpose:** The purpose of this amendment is to permit CMS to clarify the pricing standards subject to the requirements of section 173 of MIPPA to include pricing standards based on MAC and to clarify requirements of transparency of payment methodology to pharmacies.

**Description of Amendment:** This amendment would strengthen the requirement of Section 173 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) that requires Medicare Part D drug plan sponsors that use “a standard for reimbursement of pharmacies based on the cost of a drug,” to update this standard “not less frequently than once every 7 days,” beginning with an initial update at the beginning of each calendar year. Because pharmacy reimbursement is often based on the cost of prescription drugs, it is critical that pharmacists have predictable and transparent reimbursement from Part D plan sponsors.

Drug pricing standards based on the maximum allowable cost (MAC) of a drug are not being updated with the frequency required by section 173 of MIPPA. In some instances, the MAC standards are being updated after several hundred days. This runs directly counter to the goals and intention of section 173. In regulations implementing section 173, CMS failed to properly identify specific drug pricing standards subject to this requirement. In the preamble of the applicable interim final rule, CMS lists examples of pricing standards, but not an exhaustive list. By omitting certain pricing standards, a loophole has been created that will allow Part D plan sponsors to largely avoid the requirements created in section 173.

Section 173 of MIPPA is purposefully broad, and as stated, requires that a plan sponsor that uses “a [emphasis added] standard for reimbursement of pharmacies based on the cost of the drug” must update such standard at least once every seven days. Congress, by choice, did not explicitly identify specific standards or a subgroup of standards that must be updated. Rather, the requirement applies to any standard which is based on the cost of a drug. Clearly, reimbursement based on MAC falls into this broad category of a standard of reimbursement based on the cost of a drug.

## Grassley-Carper Amendment #7 to the Chairman's Mark

**Title:** Inclusion of Pharmacists as Providers in Medicare ACOs

**Purpose:** The purpose of this amendment is to encourage CMS to designate pharmacists as providers of services and suppliers within Medicare ACOs.

**Description:** Pharmacists are integral members of the patient's health care team, and ACOs engage pharmacists in a variety of patient care services as part of this team, including:

- Medication management
- Medication reconciliation/care transitions services
- Access to medications
- Chronic condition management
- Prevention through the delivery of Annual Wellness Visits, especially the medication reconciliation and screening portions.

This amendment would strengthen the role of pharmacists within Medicare ACOs by amending Section 1899 of the SSA to include licensed pharmacists as providers of services in team-based or integrated care activities with one or more of the other defined groups and suppliers. In addition to the individual patient benefits of this inclusion, on a population based level definitively integrating pharmacists into the Medicare ACO can help eliminate gaps in care by focusing on the coordination between providers and engagement of pharmacists in medication-related quality metrics.

## Grassley-Casey Amendment #8 to the Chairman's Mark

**Title:** Continuing Care Retirement Communities and Medicare Demonstration Project

**Purpose:** The purpose of this amendment is to require the Center for Medicare and Medicaid Innovation (CMMI) to eliminate the barriers in allowing Continuing Care Retirement Communities (CCRC) to receive Medicare services provided under a risk-adjusted, capitated payment arrangement.

**Description of Amendment:** This amendment would provide for comprehensive, affordable, high-quality healthcare into the homes of Medicare beneficiaries by combining established and successful models of care – PACE (Program of All-inclusive Care for the Elderly) and CCRC – to improve the efficiency and quality of senior care and align incentives to provide the right care, at the right time, in the right setting.

Medical homes, care coordination and disease management are among the most promising strategies for cost containment and quality improvement in health care delivery, especially the costs associated with Medicare beneficiaries with chronic conditions. There are currently 2,000 Continuing Care Retirement Communities in America today. Recent studies, including the *New England Journal of Medicine*, demonstrate that a congregate senior living environment such as a CCRC is actually the ideal setting to integrate these cost containment strategies to lower cost and improve outcomes for Medicare seniors because of the near-constant interaction between staff and residents.

The CCRC would accept a diverse group of independent, non-acute seniors whose mix of chronic conditions could benefit from the care coordination and disease management services provided onsite to avoid hospitalizations and lower the total cost of care for seniors as they age in place and their needs increase. An interdisciplinary health care team led by salaried primary care physicians would integrate comprehensive primary and post-acute health care services into the CCRC and coordinate acute and specialist care. Beneficiaries would receive Medicare services provided under a risk-adjusted, capitated payment arrangement.

## **Grassley Amendment #9 to the Chairman's Mark**

**Title:** Protecting Provider Licensure in Medicare and Medicaid

**Purpose:** The purpose of this amendment is to increase access to care for Medicare and Medicaid beneficiaries by limiting the ability of CMS to overrule state scope of practice and licensure.

**Description of Amendment:** This amendment would require CMS to reimburse Medicare-eligible providers for Medicare-covered Part B services to Medicare-eligible beneficiaries. The Social Security Act provides for Medicare Part B coverage of certain medical services and supplies through practitioners and physicians. To be covered by Medicare Part B, all services conducted by a Medicare approved practitioner or physician must be either medically necessary or one of several prescribed preventive benefits.

This amendment would limit the ability of CMS to create limitations on provider participations that are more restrictive than their state scope of practice and licensure. In Medicaid, states would no longer be allowed to restrict participation of providers in their state for Medicaid-covered services to Medicaid beneficiaries based strictly on scope of practice and licensure.

Licensure authority defines who has the legal responsibility to grant a health professional the permission to practice their profession. Historically, under Article X of the U.S. Constitution, states have the authority to regulate activities that affect the health, safety, and welfare of their citizens including the practice of healing arts within their borders. Laws governing individual health care providers are enacted through state legislative action, with authority to implement the practice acts delegated to the respective state licensing board. The purpose of licensing health care professionals is to protect the public from incompetent or impaired practitioners. Practicing medicine requires a certificate of licensure from the state in which the practitioner is working and may require licensure in the state where the patient is located.

Licensure generally establishes a "scope of practice" designed to protect the public. "Scope of practice" delineates what a profession does and places limits upon the functions persons within a profession may lawfully perform. It determines the procedures, actions, and processes that are permitted for the licensed individual. The scope of practice is limited to that which the law allows for specific education and experience, and specific demonstrated competency. Each state has laws, licensing bodies, and regulations that describe requirements for education and training, and define scope of practice.

The U.S. health care system is undergoing a transformation in response to a number of factors.

These include but are not limited to provisions in the health reform law, advances in technology and the aging of the population. Whatever the cause and directions of change, many analysts predict a shortage of health care providers in the next decade and beyond. By limiting the ability of CMS to overrule state scope of practice and licensure, this increases access to care and the quality of care for Medicare and Medicaid beneficiaries.

## **Grassley-Rockefeller-Carper Amendment #10 to Title XIX of the Social Security Act**

**Title:** Prevention of Diabesity Amendment

**Purpose:** The purpose of this amendment is to provide coverage of intensive behavioral therapy for obesity and the coordination of programs to prevent and treat obesity in Medicare and Medicaid. Under this amendment, coverage of diabetes prevention program services to an eligible diabetes prevention program individual will also be established. This amendment further amends section 1927(d)(2)(A) of the SSA to remove drugs for weight loss management from the List of Drugs Subject to Restriction for coverage under Medicaid and Medicare Part D.

**Description of Amendment:** This amendment encompasses S.452, The Medicare Diabetes Prevention Act of 2013 and H.R. 2415, the Treat & Reduce Obesity Act, both expanded to include Medicaid and thereby concurrently addressing the prevention and treatment of obesity and diabetes in both the Medicare and Medicaid programs. It directs the Secretary of Health and Human Services (HHS) to establish the criteria for a diabetes prevention program in accordance with the standards under the National Diabetes Prevention Program and ensure coverage of this program to eligible individuals in Medicare and Medicaid.

This amendment also directs the Secretary to allow reimbursement for intensive behavioral therapy outside of the primary care setting in both Medicare and Medicaid. In addition to qualified primary care physicians and practitioners, the Secretary will permit other physicians, registered dietitians, certified diabetes educators, and instructors trained and certified by the National Diabetes Prevention Lifestyle Coach Training program of the Centers for Disease Control and Prevention to provide and be independently reimbursed for intensive behavioral therapy for obesity. The expansion of permissible practitioners for intensive behavioral therapy for the treatment of obesity under this amendment requires the coordination of care regarding recommendations and treatment plan between these practitioners and the individual's primary care physician. This amendment would also remove prescription drugs for the treatment of obesity from the List of Drugs Subject to Restriction for Coverage on Medicare and Medicaid under section 1927(d)(2)(A) of the SSA. These drugs are defined as prescriptions for the treatment of obesity or for weight loss management for an individual who is overweight and has one or more co-morbidities.

With diabetes and obesity as major drivers of health care service utilization and spending, this amendment encompasses both S.452 and H.R. 2415, seeking the interactive effect of addressing these diseases concurrently in both Medicare and Medicaid.



## **Grassley Amendment #11 to the Chairman's Mark with Stabenow**

**Title:** Extension of Grandfather Clause for Subsidiary Educational Institutions

**Purpose:** The purpose of this amendment is to extend the “grandfather” provision for provider-owned nursing or allied health education programs to account for the lengthy and costly process of becoming wholly owned subsidiary educational institutions in compliance with HLC accreditation standards.

**Description of Amendment:** The amendment proposes that § 413.85(g)(3)(i) be amended to state:

(i) Effective for portions of cost reporting periods occurring on or after January 1, 2013, a provider that incurs costs for a nursing or allied health education program(s) may receive reasonable cost payment for such a program(s) according to the specifications under paragraphs (g)(3)(ii) and (g)(3)(iii) of this section where

(a) those program(s) had originally been provider-operated according to the criteria at paragraph (f) of this section, and then operation of the program(s) was transferred to a wholly owned subsidiary educational institution that became a wholly owned subsidiary prior to January 1, 2017 in order to meet accreditation standards and

(b) the provider has continuously incurred the costs of both the classroom and clinical training portions of the program(s) at the educational institution.

The proposed reporting period date of January 1, 2013 aligns with the effective date of the Higher Learning Commission's (“HLC”) new standards. The proposed date of January 1, 2017 accounts for the extensive and oftentimes lengthy process nursing and allied health schools must navigate to become wholly owned subsidiary educational institutions in compliance with HLC accreditation standards; extending the “grandfather” provision by over two years gives nursing and allied health educational programs the ability to separately incorporate within the timeframe proposed.

We understand this change to impact 19 schools. States with schools impacted by the issue are in Iowa, Illinois, Ohio, MO and Nebraska.

## **Grassley Amendment #12 to the Chairman's Mark**

**Title:** Sunsetting the Independent Payment Advisory Board

**Purpose:** The purpose of this amendment is to provide Congress the opportunity to review the actions taken by the Independent Payment Advisory Board and determine if it should be reauthorized.

**Description of Amendment:** The Patient Protection and Affordable Care Act of 2010 created the Independent Payment Advisory Board (IPAB), Section 1899A of the Social Security Act. This amendment sunsets IPAB as of December 31, 2020. This amendment does preserve the authority for any recommendations made under the IPAB during 2020 to be implemented during 2021 and beyond.

## **Grassley Amendment #13 to the Chairman's Mark**

**Title:** Full GPCI Permanence

**Purpose:** The purpose of this amendment is to make permanent the existing floor 1.0 on the physician work index under the Medicare physician fee schedule.

Under current law, the Medicare fee schedule is adjusted geographically for three factors to reflect differences in the cost of resources needed to produce physician services: physician work, practice expense, and medical malpractice insurance.

**Description of Amendment:** This amendment modifies Section 201 of the Chairman's Mark by striking “, modified to 0.995 for services provided during CY2015, and set at 0.99 for services provided beginning in CY2016”.

## **Grassley Amendment #14 to the Chairman's Mark**

**Title:** Review of Secretarial Authority to Adjust the Value-Based Performance (VBP) Program

**Purpose:** The purpose of this amendment is to allow for review of the exercise of Secretarial authority under the Value-Based Performance (VBP) Program.

**Description of Amendment:** This amendment would amend Section 102 of the Chairman's Mark to allow for judicial review under the Administrative Procedures Act for decisions made by the Secretary to exercise authority to reduce the variation in the VBP funding pool. The Chairman's Mark provides the Secretary authority to adjust the funding pool if the Secretary determines it appropriate. To insure that providers are not inappropriately disadvantaged based on the location of their practice, type of practice, or the health status of the patients they serve and to protect beneficiaries from potential unintended consequences, and given the potential financial magnitude of the decision, the Secretary's decision should be subject to judicial review.

## **Grassley-Rockefeller Amendment #15 to the Chairman's Mark**

**Title:** Removing Medicaid from the APM all-payer revenue calculation

**Purpose:** The purpose of this amendment is to remove Medicaid from the APM all-payer revenue calculation while providing the Secretary authority to include Medicaid revenue for certain payment models.

**Description of Amendment:** This amendment would amend Section 102 of the Chairman's Mark to remove Medicaid from the APM all-payer calculation. The Secretary would be given the authority to allow providers to self-select to include their Medicaid revenue in the all-payer APM revenue calculation.

The Secretary would instruct CMMI to consider additional APM models appropriate for Medicaid providers, and that the revenue reporting for the provider could be achieved in a timely manner. This would include Medicaid medical homes with criteria similar to medical homes expanded under 1115A(c) as attributable to items and services to which the professional is provided payment based on an alternative payment model.

## **Grassley Amendment #16 to the Chairman's Mark**

**Title:** Funding for OIG

**Purpose:** The purpose of the amendment is to provide for the improved use of funds received by the HHS Inspector General from oversight and investigative activities.

**Description of Amendment:** The Office of the Inspector General protects the integrity of HHS programs and the health and welfare of the people they serve. OIG is responsible for providing oversight of nearly \$1 trillion in HHS spending oversight, or about \$0.24 of every Federal dollar. OIG fights fraud, waste, and abuse throughout HHS programming, however as this responsibility grows with the expansion of HHS programs and oversight of the ACA, funding resources for OIG have faced significant cuts. This amendment allows the Inspector General of the Department of Health and Human Services to receive and retain three percent of all collections pursuant to civil debt collection actions related to false claims or frauds involving the Medicare program under title XVIII or the Medicaid program under title XIX. These funds would then be available for oversight and enforcement activities of the Inspector General in order to provide the resources to pursue its mission in fighting fraud, waste, and abuse.

## **Grassley Amendment #17 to the Chairman's Mark**

**Title:** MACPAC Study of TMA Churning

**Purpose:** The purpose of this amendment is to instruct MACPAC to perform a study of churning amongst individuals eligible for transitional medical assistance (TMA).

**Description of Amendment:** This amendment would instruct MACPAC to undertake a study of churning including amongst individuals eligible for transitional medical assistance (TMA). One of the challenges in making decisions about longer-term policy on transitional medical assistance is the lack of information related to the income of individuals eligible for the benefit. As an individual's income changes, the individual's eligibility for Medicaid or TMA may change several times over a twelve to 24 month period. Understanding the volatility in income for these individuals will be helpful in informing future policy making.

Under this amendment, HHS and CMS will be instructed to provide data on average monthly TMA enrollment and average monthly TMA participation rates, and the number and percentage who end up in another Medicaid pathway or on CHIP once their TMA ends.

## **Grassley Amendment #18 to the Chairman's Mark**

**Title:** Full Substitute to the SGR Title of the Chairman's Mark

**Purpose:** The purpose of this amendment is to replace the Sustainable Growth Rate formula while still keeping pressure on all stakeholders to work towards a long-term payment solution.

**Description of Amendment:** This amendment would strike Section 102 of the Chairman's Mark and replace it with the following.

- An update of 1% for the SGR in FY2014.
- Repeal of the SGR as of September 30, 2014.
- Physician payment rates for FY2015 are frozen at FY2014 levels.
- For each succeeding year after FY2015, the physician payment rate is reduced by 1%.



## **Crapo Amendment #1 to Chairman's Mark on SGR**

**Short Title:** Preventing tax increases on the middle class

**Description of Amendment:** This amendment would nullify any tax, fee or penalty imposed by the Patient Protection and Affordable Care Act on any individual earning less than \$200,000 per year or any couple earning less than \$250,000 per year.

## **Roberts and Casey Amendment #1 to the Chairman's Mark**

**Title:** Expansion of MTM targeted beneficiary

**Purpose:** The purpose of this amendment is to expand the definition of targeted beneficiary with respect to medication therapy management.

Under current law, a targeted beneficiary must have multiple chronic diseases.

**Description of Amendment:** This amendment amends part D (Voluntary Prescription Drug Benefit Program) of title XVIII (Medicare) of the Social Security Act to direct the Chief Actuary of the Centers for Medicare and Medicaid Services to report to the Secretary of Health and Human Services (HHS) and to Congress on whether or not the expansion of the definition of targeted beneficiary, with respect to medication therapy management, would, if implemented, reduce spending under Medicare. Requires the report to include a certification of any determination by the Chief Actuary that such expansion would reduce such spending.

Specifies such an expansion as targeted beneficiaries with a single chronic disease that accounts for high Medicare spending, including diabetes, hypertension, heart failure, dyslipidemia, respiratory disease (such as asthma, chronic obstructive pulmonary disease, or chronic lung disorders), bone disease-arthritis (such as osteoporosis or osteoarthritis), rheumatoid arthritis, and mental health (such as depression, schizophrenia, or bipolar disorder).

Requires such an expansion to take place if the report contains the certification indicated.

## **Roberts and Enzi Amendment #2 to the Chairman's Mark**

**Title:** Clarification of 96 Hour rule for Critical Access Hospital Conditions of Participation

**Purpose:** The purpose of this amendment is to revise physician certification requirements for inpatient critical access hospital services. The amendment would remove the condition of payment for CAHs that requires a physician to certify that each patient will be discharged/transferred in less than 96 hours. The condition of participation requiring CAHs to maintain a 96 hour annual average per patient would remain.

Under current law, CMS has required CAHs to meet the condition of participation and maintain a 96 hour annual average length of stay. Through recent guidance, CMS has clarified they will also begin enforcing the condition of payment requiring physician certification that each patient will stay for 96 hours or less.

**Description of Amendment:** This amendment would amend Section 1814(a) of the Social Security Act (42 U.S.C. 1395f(a)) but removing paragraph 8 and making the conforming amendments to paragraph 6 and 7, including the addition of 'and' between paragraph 6 and 7.

## **Roberts and Thune Amendment #3 to the Chairman's Mark**

**Title:** Durable Medical Equipment Competitive Bidding Clarification

**Purpose:** The purpose of this amendment is to provide additional requirements for bidders under the DME CB program. Specifically to require bidders to be licensed and accredited to provide products or services in the state or geographic area for which they submit and win a bid. They must maintain this licensure and accreditation during the time in which they are under contract for the winning bid, not doing so will put them in violation of the contract and would prohibit them from providing the products or services in that state or geographic area. In addition the bidder must have a physical presence, or a physical presence in a contiguous state not to exceed 50 miles from the state or geographic area, for which they are submitting a bid.

Under current law CMS requires licensure and accreditation however further clarification is necessary for where that bidder must be licensed and accredited and for where they are bidding to provide the service.

**Description of Amendment:** This amendment would amend Section 1834(b)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(b)(2)(A)) by adding at the end a new clause requiring licensure and accreditation in the states or geographic areas for which the bid is submitted and where the entity wins the bid. This licensure and accreditation must be maintained throughout the time of the contract. In order to be eligible for submitting a bid the entity must maintain a physical presence in the state, or contiguous state not to exceed 50 miles from the geographic area, in which the bid is submitted, and the entity provides products or services.

## **Roberts Amendment #4 to the Chairman's Mark**

**Title:** Ensure Regulatory Accountability and Transparency of Implementation

**Purpose:** This amendment would add an implementation section specifying how regulations implementing the Act must be issued.

**Description of Amendment:** This amendment would add an implementation section to the end of the Act specifying requirements for all regulations implementing any section of the Act.

Implementation section:

In promulgating any regulations to implement this Act (and the amendments made by this Act), the Secretary of Health and Human Services shall—

- (1) issue a notice of proposed rulemaking that includes the proposed regulation;
- (2) provide a period of not less than 60 calendar days for comments on the proposed regulation;  
and
- (3) publish the final regulation or take alternative action (such as withdrawing the rule or proposing a revised rule with a new comment period) on the proposed regulation, not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.

## **Roberts Amendment #5 to the Chairman's Mark**

**Title:** ObamaCare Repeal Amendment

**Purpose:** To fully repeal the PPACA and HCERA.

**Description of Amendment:** This amendment repeals the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, effective as of their enactment. Restores provisions of law amended by such Acts.

## **Roberts Amendment #6 to the Chairman's Mark**

**Title:** Preserving Access to Targeted, Individualized, and Effective New Treatments and Services (PATIENTS) Act of 2013

**Purpose:** To ensure comparative effectiveness research may not be used to ration patient care by delaying or denying coverage of an item or service.

**Description of Amendment:** This amendment prohibits the Secretary of Health and Human Services (HHS) from using data obtained from comparative effectiveness research, including any conducted or supported using funds appropriated under the American Recovery and Reinvestment Act of 2009 (ARRA) or authorized or appropriated under the Patient Protection and Affordable Care Act, to deny or delay coverage of an item or service under a federal health care program. Requires the Secretary to ensure that comparative effectiveness research conducted or supported by the federal government accounts for factors contributing to differences in the treatment response and preferences of patients, including patient-reported outcomes, genomics and personalized medicine, the unique needs of health disparity populations, and indirect patient benefits.

## **Roberts Amendment #7 to the Chairman's Mark**

**Title:** Repeal the Individual Mandate Amendment

**Purpose:** To repeal the individual mandate requirements of the PPACA.

**Description of Amendment:** This amendment repeals provisions of the Patient Protection and Affordable Care Act that require individuals to maintain minimum essential health care coverage. Applies the Internal Revenue Code as if such provisions had never been enacted.



## **Roberts Amendment #8 to the Chairman's Mark**

**Title:** Restoring Access to Medication Act

**Purpose:** To amend the Patient Protection and Affordable Care Act to repeal distributions for medicine qualified only if for prescribed drug or insulin.

**Description of Amendment:** This amendment repeals provisions of the Patient Protection and Affordable Care Act that limit patients' ability to purchase over the counter medication. Section 9003 of the Patient Protection and Affordable Care Act (Public Law 111-148) and the amendments made by such section are repealed, and the Internal Revenue Code of 1986 shall be applied as if such section, and amendments, had never been enacted.

**Enzi (with Carper) Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to allow physician assistants (PAs) to provide and manage hospice care for Medicare beneficiaries.

**Description of Amendment:** This amendment seeks to amend Section 1861(dd)(3)(B) and Section 1814(a)(7)(A)(i)(I) of the Social Security Act to allow physician assistants to provide and manage hospice care services for Medicare beneficiaries. The amendment does not include the authority to order hospice care for Medicare beneficiaries.

## **Enzi Amendment #2 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to title XVIII of the Social Security Act to provide for fairness in hospital payments under the Medicare program.

**Description of Amendment:** This amendment seeks to amend Section 3141 of the Patient Protection and Affordable Care Act to make budget-neutral changes to the floor for Medicare hospital wage index calculations. Specifically, this amendment would rescind the calculation of the hospital wage index floor on a national basis and would require CMS to calculate the Medicare hospital wage index floor on a state-by-state basis, as under prior law. This change would be effective October 1, 2014.

### **Enzi Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to require the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to seek public comment on whether proposed Medicare payment policies will increase or decrease the consolidation of health care providers.

**Description of Amendment:** This amendment would require HHS and CMS, in any future rulemaking to implement changes to Medicare payments for hospitals, post-acute care providers, physicians, or other health care professionals done through the notice-and-comment process, to request public comment on whether or not the proposed policy would create incentives or disincentives for providers affected by the rule to consolidate or merge. Since a lack of competition generally results in fewer choices and higher prices, the intent of this amendment is to gather more data on the economic impact of market consolidation in the health care sector on access, pricing, and cost.

**Enzi (with Crapo) Amendment #4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to allow individuals to keep their health insurance plans if they like them.

**Description of Amendment:** This amendment would allow health insurance issuers to continue to offer any health insurance plan that was in effect as of January 1, 2013 or plan year 2013. Family members eligible to enroll in these plans shall also remain eligible to enroll in a plan. Issuers may also accept new enrollees into these plans. Individuals enrolled in these plans will be considered to have coverage in a qualified health plan and therefore not subject to the individual shared responsibility requirement.

## **Enzi Amendment #5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to allow health insurance issuers to offer any insurance product on a state-based or federal exchange.

**Description of Amendment:** This amendment would repeal the language in the Patient Protection and Affordable Care Act that prohibits issuers from offering health insurance plans in the state-based and federal health insurance exchanges that do not cover all “essential health benefit” categories. Any health insurance plan offered by insurers for plan year 2014 or beginning January 1, 2014 will be eligible for inclusion in a state-based or federal exchange, subject to approval by the state insurance commissioner.

## **Enzi Amendment #6 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to modernize the Medicare benefit through bipartisan, common-sense reforms.

**Description of Amendment:** This amendment would simplify the basic structure of Parts A and B, reduce the distortions as well as higher costs that many seniors pay that result from first-dollar Medigap coverage, protect low-income seniors from catastrophic medical costs, and better align Medicare premiums with a senior's ability to pay. Specifically, the amendment would establish: a unified Medicare Part A and Part B deductible of \$550; a unified coinsurance rate of 20% for beneficiaries for Medicare Parts A and B services; a cap on annual Out-of-Pocket (OOP) expenses for Medicare beneficiaries; a prohibition on first dollar Medigap coverage; and increased income-related adjustments to beneficiary premiums for Medicare Parts B and D.

## **Enzi Amendment #7 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to modernize the Medicare benefit through bipartisan, common-sense reforms.

**Description of Amendment:** This amendment would make the Medicare benefit more equitable and sustainable by increasing income-related adjustments to beneficiary premiums for Medicare Parts B and D. These adjustments are based on the proposal in the President's FY 2014 Budget.



## **Enzi Amendment #8 to the SGR Repeal and Medicare Beneficiary Access Improvement Act of 2013**

**Short Title:** An amendment to improve incentives for individuals to utilize and employers to offer medical flexible spending accounts (FSAs).

**Description of Amendment:** This amendment would amend the Internal Revenue Code to allow amounts in a flexible spending arrangement (FSA) that are not spent for medical care to be distributed to the FSA participant as taxable income after the close of a plan year (currently, such unspent amounts are forfeited). The amendment also includes such FSAs in the definition of tax-exempt cafeteria plans.

## Cornyn Amendment #1 to the Chairman's Mark-

Short Title: Protect seniors from a board of 15 bureaucrats empowered to make substantial changes to the Medicare without full transparency and accountability

Description of Amendment: This amendment would repeal the Independent Payment Advisory Board (IPAB), created by sections 3403 and 10320 of the Patient Protection and Affordable Care Act. The IPAB threatens seniors' access to care through the establishment of a 15 member panel of unelected government officials who have the authority to unilaterally slash Medicare reimbursement rates. The IPAB is prohibited from making recommendations that raise revenues or Medicare beneficiary premiums, increase beneficiary cost-sharing, or modify eligibility criteria. The IPAB is essentially reduced to making provider cuts to reach arbitrary global budget targets. Reduction of provider payments to unsustainable levels amounts to rationing of care. Repeal of the IPAB would protect the rights of patients, families, and doctors to make medical decisions.

Cornyn Amendment #2 to the Chairman's Mark-

Short Title: Provide premium pricing transparency for Americans

Description of Amendment: This amendment would shed more transparency on the rising costs of health care premiums due to taxes and fees required by the Patient Protection and Affordable Care Act (PPACA). Health plans would be required to disclose in writing to consumers the annual fees and taxes (annual fee on health insurance issuers, Patient Centers Outcome Research Institute tax, reinsurance contributions, health insurance exchange user fees, risk corridor payments, risk adjustment charges) imposed by the PPACA. It would also require the Government Accountability Office (GAO) to conduct and publish a study of methods of calculating the impact on average premium costs associated with PPACA mandates.

Cornyn Amendment #3 to the Chairman's Mark-

Short Title: Repeal the federal navigator program

Description of Amendment: This amendment would repeal the troubled federal navigator program created under the Patient Protection and Affordable Care Act (PPACA). As navigators assist individuals with enrolling on the exchanges they will have access to consumers' personally identifiable information, such as date of birth, social security number, and tax information. However, the Department of Health and Human Services only established minimal federal requirements for individuals who could be certified as navigators and background checks are not required. Repeal of this program would protect Americans from passing their personally identifiable information to a navigator with a criminal background.

## Cornyn Amendment #4 to the Chairman's Mark-

Short Title: Ensure Americans receive notification if their personal information is at risk

Description of Amendment: The troubled launch of the federal health care exchange website and concerns with the government database raise serious questions about the security of Americans' personal information. This amendment would require the federal government to notify consumers who have created an account or enrolled in health care coverage through the federal health care exchanges if there is a security breach and their personal information is compromised.

## Cornyn Amendment #5 to the Chairman's Mark-

**Short Title:** Maintain the audit programs designed to identify fraud, waste, and improper billing while promoting fairness by allowing providers to rebill claims

**Description of Amendment:** Where claims originally denied by a Medicare Administrative Contractor (MAC), Recovery Audit Contractor (RAC), or Comprehensive Error Rate Testing (CERT) contractor are determined to be appropriate at the outpatient rate, these claims may be rebilled. In order to ensure rebilling may occur, the Secretary is required to ensure that the lookback period for the audits is equal to the period of time allowed for providers to rebill claims. The Secretary may provide a short period of time (such as one month) for providers to rebill following final adjudication of claims.

## Cornyn Amendment #6 to the Chairman's Mark-

Short Title: Establish interoperability of electronic health records

Description of Amendment: As part of the notice and comment rulemaking for Stage 3 of the meaningful use electronic health record (EHR) program, the Secretary would be required to adopt a common standard for the interoperability of electronic health records (EHRs) by 2017. The American Recovery and Reinvestment Act of 2009 (ARRA) created the Meaningful Use program, which provides incentives to physicians and hospitals for the adoption of EHRs. However, interoperability or the ability to share records between hospitals and physician practices remains limited because a common standard is not used. To truly establish meaningful use of EHRs, the systems must be able to communicate with each other.

Cornyn Amendment #7 to the Chairman's Mark-

Short Title: Ensure that physicians are not required by the federal government to contract with a particular health plan as a condition of state licensure

Description of Amendment: This amendment would prohibit the federal government from requiring a health care provider to participate in Medicare, Medicaid, or any health plan as a condition of the provider's licensure in any state.



Cornyn Amendment #8 to the Chairman's Mark-

Short Title: Require testing of ICD-10 prior to full implementation

Description of Amendment: Under the Health Insurance Portability and Accountability Act, physicians are currently required to transition from the International Classification of Diseases version 9 (ICD-9) to ICD-10 for purposes of reporting medical diagnoses by October 1, 2014. ICD-9 has approximately 13,000 codes while ICD-10 includes 68,000 codes.

This amendment would require the Centers for Medicare and Medicaid Services to beta test implementation of ICD-10 prior to full implementation. It would also require the Government Accountability Office to certify CMS' methodology and determinations prior to full implementation of ICD-10.

Cornyn-Cardin Amendment #9 to the Chairman's Mark-

Short Title: Evaluate the effectiveness of technical assistance funding and its impact on physicians practicing in rural areas and HPSAs

Description of Amendment: As part of the studies submitted to Congress on October 1, 2018 and October 1, 2021, the GAO shall specifically evaluate the impact of technical assistance funding on the ability of providers (especially physicians in rural areas or HPSAs, and physicians treating other underserved populations) to improve within the VBP or successfully transition to APMs. The report would also provide recommendations for maximizing use of these technical assistance funds.

Cornyn-Cardin Amendment #10 to the Chairman's Mark-

Short Title: Evaluate the ability of physicians practicing in rural areas and HPSAs to transition from fee-for-service to APMs

Description of Amendment: The GAO shall submit a report to Congress on October 1, 2019 and October 1, 2021 on the transition of physicians in rural areas and HPSAs and physicians treating other underserved populations to APMs. The studies shall make recommendations on changes that could be made to overcome barriers for rural providers and those in HPSAs to participate in APMs.

Cornyn Amendment #11 to the Chairman's Mark-

Short Title: Ensuring broad stakeholder representation in quality measure endorsement and selection

Description: This amendment would require that any entity that has a contract with the Federal government regarding input on the selection of quality or resource use measures shall include broad stakeholder representation on its governance board and through its endorsement process, including representation from Medicare suppliers and manufacturers of health care products, consistent with the existing governance and operation of the National Quality Forum.

## Cornyn Amendment #12 to the Chairman's Mark-

Short Title: Increasing transparency by ensuring all stakeholders have an opportunity to provide comments on resource use methodology

Description of Amendment: In seeking comments on developing a classification system and codes for the purposes of classifying similar patients into distinct care episode and patient condition groups for purposes of measuring resource use, the Secretary would be required to go through notice and comment rulemaking. This would provide transparency by ensuring that stakeholders have a full opportunity to review the proposed resource use methodology and comment appropriately. The Secretary is required to take into account the importance of measures endorsed by a consensus-based entity for use at the physician level.

## **Thune-Bennet-Enzi-Roberts Amendment #1 to the Chairman's Mark**

**Short Title:** This amendment provides a legislative clarification on the level of physician supervision that is required for outpatient supervision of therapeutic services at critical access hospitals.

**Description of Amendment:** This amendment would allow general supervision by a physician or non-physician practitioner at critical access hospitals for payment of therapeutic hospital outpatient services. This stemmed from confusion over the 2009 Medicare outpatient prospective payment system final rule where CMS issued a new policy regarding direct physician supervision of outpatient therapeutic services. Many health care organizations, particularly critical access hospitals, recognized the release of this rule as a burdensome and unnecessary new policy change, but CMS characterized the change as a "restatement and clarification" of existing policy in place since 2001.

Additionally, non-physician practitioners at critical access hospitals may directly supervise cardiac and pulmonary rehab. This fixes a technical problem that prohibits non-physician practitioners from directly supervising cardiac and pulmonary rehabilitation services.

This amendment would also hold all hospitals harmless from civil or criminal action for failing to meet CMS' direct supervision policy clarified in a 2009 rule and in subsequent regulations and program manuals, for the period 2001 through 2014. After the release of the rule, CMS issued statements of non-enforcement while stakeholders provided comments on the impact of implementation, and this amendment seeks to address this.

## **Thune-Casey-Enzi Amendment #2 to Chairman's Mark**

**Short Title:** To provide a demonstration project on remote patient monitoring (RPM) in the Medicare program to ensure seniors can remain in their homes longer and to prevent hospital readmissions.

**Description of Amendment:** This amendment is based on the stand-alone Fostering Independence Through Technology Act and would require the Secretary of Health and Human Services to create pilot projects that incentivize home health agencies and other entities to purchase and utilize remote patient monitoring and communications technologies.

Analyses of existing RPM programs show that utilizing this technology can keep seniors in their home longer and avoid unnecessary transfers to higher acuity and higher cost facilities. These studies also show that using RPM can reduce hospital readmissions and increase patient satisfaction.

Each year home health agencies participating in the pilot will receive an incentive payment based on a percentage of the Medicare savings realized as a result of the pilot projects. The incentive payments in the aggregate, however, may not exceed the amount that the Secretary estimates would be expended to home health agencies if the pilot projects had not been implemented. These technologies must both enhance health outcomes for Medicare beneficiaries and reduce total spending under the Medicare program.

Incentive payments shall not reduce the payments that home health agencies would otherwise receive for providing home health benefits to Medicare beneficiaries, and performance targets would be established based on historic spending in Medicare. This target will be used to determine if the projects are enhancing health outcomes for Medicare beneficiaries and saving the program money.

The amendment requires that pilot projects be conducted in both urban and rural areas and that at least one project be conducted in a state with a population of less than one million.

The amendment would also direct the secretary to establish a study (or technical commission) to further the goals of the Value Based Performance incentive program by establishing a Commission of technical experts to study and develop recommendations for proper valuation and payment of remote monitoring services reimbursed under the Medicare physician fee schedule to more accurately capture the resources used in providing these services.

### **Thune-Enzi Amendment #3 to the Chairman's Mark**

**Short Title:** Requiring Interoperability in the Meaningful Use Program by 2017.

**Description of Amendment:** This amendment would require interoperability be achieved by 2017 to be a meaningful user under the Electronic Health Record Meaningful Use program. To determine the interoperability standards, the Secretary shall go through the process required through the National Coordinator for Health IT and the HIT Standards Committee.



## **Thune-Rockefeller Amendment #4 to the Chairman's Mark**

**Short Title:** Providing Additional Technical Assistance to Small Rural Practices in the Value Based Performance (VBP) Program.

**Description of Amendment:** This amendment would specify that \$10 million of the \$25 million available each year from 2014 to 2018 to provide technical assistance through quality improvement organizations, or other ways to directly assist providers, be available solely for assistance to small practices of ten or fewer eligible professionals located in Health Professional Shortage Areas. This funding is to be used to help practices succeed in the VBP program or to move to an Advanced Payment Model.

The original proposal from the Finance Committee released on October 30, 2013, included \$10 million for this purpose for small practices of ten or fewer eligible professionals located in Health Professional Shortage Areas or rural areas. The modified mark included \$25 million but broadened the eligibility to include physicians in non-rural areas.

Targeting \$10 million of the \$25 million available each year from 2014 to 2018 to rural practices is in line with what the Committee originally identified.

## **Thune-Wyden-Roberts- Rockefeller -Enzi -Stabenow Amendment #5 to the Chairman's Mark**

**Short Title:** Promote use of telehealth technology by ensuring payment and eligibility barriers to using telehealth do not exist in the Alternative Payment Models (APM).

**Description of Amendment:** This amendment would ensure that the geographic and code restrictions in §1834(m) of the Social Security Act do not apply to any APMs. This would mean that §1834(m) restrictions do not apply to accountable care organizations, bundled payments, medical homes, or any other models developed to be an APM.

Section 1834(m) of the Social Security Act states that telemedicine can only be reimbursed when the patient is at a qualified "originating site," which is a doctor's office, hospital, community health center, etc. located in a rural area known as a non-Metropolitan Statistical Areas, which are geographic areas determined by the Census Bureau. As a result, only some rural areas are eligible to participate in the Medicare telehealth program. This amendment would ensure that providers who move into an APM are free to use telehealth technology to enhance patient outcomes and improve quality regardless of the statutory restrictions in §1834(m).

## **Thune-Carper-Cornyn Amendment #6 to the Chairman's Mark**

**Short Title:** Requiring transparency in the Alternative Payment Model (APM) development.

**Description of Amendment:** This amendment would encourage an open and transparent process for CMS to follow in developing, implementing, and evaluating new APMs.

In particular, the amendment requires that the Secretary shall:

1. Provide opportunity for notice and public comment on a) draft solicitations for physician participation in new APMs and medical homes before the solicitations are finalized, and b) pilot APMs proposed for broader adoption.
2. Publicly release information describing the basis for approval of APMs; how cost and quality of care in APMs will be evaluated; results and key data supporting APM evaluations; methods for calculation of APM Baseline spending, spending targets, and any bonus payments awarded and savings achieved.
3. Report on the anticipated impact of the APM on quality of care, long-term health outcomes, and access to new tests and treatments, based on APM pilots and other related evidence, prior to entering into new APM agreements with providers.
4. Provide and release to the public an annual report to Congress on progress in the development and implementation of APMs and medical homes, including:
  - a. An assessment of the impact of APMs and medical homes on controlling overall healthcare costs; improving health outcomes for a broad range of conditions in the Medicare population; enhancing quality; promoting patient-centeredness and engagement; and supporting patient access to novel tests and treatments. This assessment should include input from the perspective of patients, physician specialty medical societies, and clinical experts from the National Institutes of Health.
  - b. Notice of any proposed changes to VBP or to APMs to be implemented over the coming year.

## **Thune Amendment #7 to the Chairman's Mark**

**Short Title:** To address the application of the low-volume payment adjustment in the end-stage renal dialysis prospective payment system.

**Description of Amendment:** The amendment directs the Secretary of Health and Human Services to apply the low-volume adjustment as defined in 42 CFR 413.232 to facilities where a change of ownership does not result in a new provider number but impacts the ability of the facility to meet the eligibility criteria of three consecutive 12 -month cost reports.

## **Thune-Isakson Amendment #8 to the Chairman's Mark**

**Short Title:** Ensuring maximum physician-led participation in the Alternative Payment Model.

**Description of Amendment:** This amendment would require that the Secretary create a demonstration, or other avenue, for physician-led Alternative Payment Models. The parameters of such payment model would allow independent physician practices to contract directly with CMS like the current Accountable Care Organization model permits to take on two-sided financial risk and responsibility for their patient population utilizing the data analytic, population management, and/or any other necessary expertise from a third-party contractor that has access to Medicare claims data, solely for this specified activity. The third-party contractor must consent to stringent data use restrictions as established by CMS and such data may not be used for medical malpractice claims.

## **Thune Amendment #9 to the Chairman's Mark**

**Short Title:** To ensure that the reinsurance fee for the transitional reinsurance program under the Patient Protection and Affordable Care Act be applied equally to all health insurance insurers and group health plans.

**Description of Amendment:** The Patient Protection and Affordable Care Act levied a reinsurance tax that will be paid by self-insured health care plans. This amendment would seek to ensure that the administration cannot grant waivers from the reinsurance tax to any self-insured health care plan.

## **Isakson Amendment #1 to the SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** Demonstration Project to Test Physician Private Contracting in Medicare

**Description:**

Current Law – Physicians who enter into private contracts with Medicare beneficiaries are required to opt out of Medicare for two years. According to the Centers for Medicare and Medicaid Services, nearly 10,000 physicians who had previously accepted Medicare opted out of the program in 2012, three times the number in 2009. Under current law, these physicians are not permitted to treat any Medicare beneficiaries at Medicare rates.

Amendment – CMS would be directed to launch a demonstration program in up to 5 states to test whether reducing restrictions on private contracting would increase Medicare beneficiaries' access to physician services. Under the demonstration, physicians could enter into private contracts with beneficiaries without being excluded from the Medicare program. Physicians would not be permitted to enter into private contracts with low-income beneficiaries or with beneficiaries facing an emergency medical condition or urgent health care situation. CMS would be required to report back to Congress on how many physicians and beneficiaries elected to enter private contracts, the impact of the demonstration on program costs, and the effect on beneficiary access to physician services with a particular focus on rural areas.

## **Isakson Amendment #2 to SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** Repeal of Medicare and Medicaid Disproportionate Share Hospital Cuts in Non-Expansion States

### **Description:**

Current Law – Beginning in fiscal year 2014, Medicare Disproportionate Share Hospital (DSH) payments are reduced to 25 percent of their previous level, plus an add-on payment based on the national uninsured rate and the amount of uncompensated care provided by a qualifying hospital. Also, beginning in fiscal year 2014, Medicaid DSH payments are reduced. The law specifies that the national aggregate reduction in Medicaid DSH payments shall be \$500 million in FY 2014, increasing to \$5 billion by FY 2018. In its final rule implementing the Medicaid DSH reductions, the Centers for Medicare and Medicaid Services stated that they will not consider states' decisions on Medicaid expansion in allocating the cuts.

Amendment – The Medicare DSH reductions would apply only to hospitals in states that have elected to participate in the expansion of Medicaid under the Patient Protection and Affordable Care Act. Additionally, the Medicaid DSH reductions would apply only to states that are expanding Medicaid. The aggregate Medicaid DSH reduction amounts described in current law would be reduced by the amount of reductions that would have been allotted to non-expansion states.



## **Isakson Amendment #3 to the SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** MedPAC Study of Brokerage for Medicare Non-Emergency Medical Transportation Services

### **Description:**

Current Law – Medicare covers ambulance service where the use of other methods of transportation is inappropriate for the beneficiary’s condition. This may include non-emergency medical transportation in certain cases, including transportation for dialysis services for beneficiaries with end-stage renal disease (ESRD). Section 1902(a)(70) of the Social Security Act permits state Medicaid programs to establish a non-emergency medical transportation brokerage program in order to more cost-effectively provide transportation for eligible beneficiaries. Under this option, states may contract with a broker to manage non-emergency medical transportation benefits.

Amendment – The amendment directs the Medicare Payment Advisory Commission (MedPAC) to study and report to Congress on whether a brokerage system would be a feasible and effective option for managing non-emergency medical transportation under the Medicare ambulance benefit to eliminate fraud and abuse, reduce program costs, and ensure that beneficiaries have access to needed transportation services as appropriate for their health status.

**Isakson Amendment #4 to the SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** Strike Extension of Health Workforce Demonstration Project

**Description:**

The amendment would strike Section 224 of the Chairman's Mark, relating to extension of a health workforce demonstration project for low-income individuals.

## **Isakson Amendment #5 to the SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** Require Background Checks for Navigators

**Description:**

Current Law – The Patient Protection and Affordable Care Act directs health benefit exchanges to award grants to navigators to conduct public education activities, distribution information regarding health coverage options, and facilitate enrollment in qualified health plans. The Secretary of Health and Human Services is directed to establish standards for qualifications and licensure of navigators.

Amendment – The amendment would add a requirement that entities receiving navigator grants perform a background check on employees providing navigator services, and prohibit individuals found guilty of crimes involving deceit or dishonesty, including identity theft, from serving as navigators.

## **Isakson Amendment #6 to the SGR Repeal and Medicare Beneficiary Access Improvement Act**

**Short Title:** Bundled Payments for Certain Radiosurgery Claims

**Description:**

The amendment directs the Centers for Medicare and Medicaid Services (CMS) to establish a bundled payment rate to pay for certain radiosurgery treatments, along with a magnetic resonance imaging (MRI) procedure and other services that are typically provided to a radiosurgery patient on the same day.

## **Portman Amendment #1 to the Chairman's Mark**

**Short title:** Health Coverage Tax Credit Extension

**Purpose:** To extend the Health Coverage Tax Credit (HCTC) for two years

**Description of Amendment:** This amendment extends the Health Coverage Tax Credit (HCTC) for two years. The HCTC is a vital tool for many Americans who have experienced job loss and receive Trade Adjustment Assistance or have had their defined benefit pension plans taken over by the Pension Benefit Guaranty Corporation. Often the HCTC serves as an important bridge for Americans until they become eligible for Medicare benefits. This amendment extends the HCTC at the current level that covers 72.5% of health insurance premiums, which was reached after bipartisan negotiations in 2011 and will expire on January 1, 2014.

## **Portman-Cardin-Stabenow-Casey Amendment #2 to the Chairman's Mark**

**Short title:** Amendment to Ensure Medicare Beneficiary Access to Durable Medical Equipment

**Purpose:** To assure compliance with state licensure requirements in the Durable Medical Equipment (DME) competitive bidding program

**Description of Amendment:** This amendment would require proof of state licensure to gain the right to submit a bid in a state in which the supplier is not currently doing business and it would limit expansion in any single year to no more than five (5) new Competitive Bid Areas (CBAs) i.e. where the supplier has no presence/does no business, and no more than two (2) product categories the supplier is not currently doing business in.

Only after these requirements are met would compliant bids be accepted.

## **Portman Amendment #3 to the Chairman's Mark**

**Short title:** Amendment to Improve Coordination in Behavioral Health Information Technology

**Purpose:** To include behavioral health providers in the HITECH Act

**Description of Amendment:** This amendment would add the following providers to the HITECH Act:

- Psychiatric hospitals defined under Section 1861(f) of the Social Security Act
- Community Mental Health Centers (CMHCs) defined under Section 1913(c)(1) of the Public Health Service Act
- Clinical psychologists defined under Section 1861(ii) of the Social Security Act
- Inpatient and outpatient addiction treatment providers who meet stringent national accreditation requirements [e.g., JCAHO, CARF, or COA].

Unlike physicians, hospitals and other eligible professionals, behavioral health providers would only be eligible for three (3) years of Medicare and Medicaid reimbursement under the HITECH Act. Nonetheless, these providers would be required to meet Meaningful Use regulatory standards. Because of the shortened reimbursement window, the Medicare penalty for these providers would be suspended.

**Contact:** Joe Shonkwiler (4-0366)

## **Toomey-Carper Amendment #1 to the Chairman's Mark**

**Title:** Standard of Care Protection

**Purpose:** Create a rule of construction in federal statute that would clarify that lawsuits could not be based solely on whether medical providers followed, implemented, or otherwise successfully achieved the national guidelines, practice standards, or other quality measures created in federal health laws.

**Description of Amendment:** The development, recognition, or implementation of any guideline or other standard under any Federal health care provision shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim.

Over the last decade, the federal government has moved to tie payments to providers under Medicare and Medicaid to their compliance with measures designed to improve cost efficiency and health care quality. Examples of national guidelines created in health laws include, the Physician Quality Reporting System (PQRS) and the Hospital Readmissions Reduction Program.

Federal efforts to tie Medicare and Medicaid payment rules to various incentives intended to promote improvements in cost efficiency and the quality of care has generally been supported on a bipartisan basis. However, the rules that have been implemented have not been developed with the intent that they should be applied in medical professional liability cases to determine the applicable standard of care.

This amendment does not amend or change Medicare or Medicaid. Nor does it change the rules of evidence or processes articulated in state law to resolve liability cases.



## **Toomey-Carper Amendment #2 to the Chairman's Mark**

**Title:** GAO Report on Opportunities for Quality Measure Alignment

**Purpose:** Request that the GAO report submitted to Congress within 18 months of enactment under Section 102, evaluate opportunities for aligning performance measure specifications and reporting requirements under the Medicare fee-for-service program, the Medicare Advantage program, and selected state Medicaid programs and private payer arrangements, particularly with regard to those measures that cut across the Medicare population and the non-Medicare population (those under 65) which are addressed in PQRS and EHR.

### **Description of Amendment:**

In some cases the Medicare fee-for-service program, the Medicare Advantage Program, state Medicaid programs and private payers have stipulated different specifications for quality measure reporting. For example, one payer may require that providers reporting hemoglobin A1c control measure report the percent of eligible patients with an HbA1c level below 8, another may request reporting on eligible patients with an HbA1C below 7, and a third may require reporting on the proportion of patients with an HbA1C greater than 9. The objective of addressing hemoglobin A1c levels, to control blood sugar for those with diabetes, is consistent across all payers, yet the potential variation in reporting requirements places additional burden on providers which could be remediated. Providers are presently required to ensure that the data they collect adheres to each payers specifications, ensuring accuracy in the numerators and denominators required to calculate a provider's compliance with each payer's performance measure.

This amendment specifies that the GAO report on quality measures required under Section 102 should evaluate opportunities to build alignment of performance measure specifications into the process of developing and updating quality measurement under the Medicare fee-for-service program, the Medicare Advantage program, and selected state Medicaid programs and private payer arrangements, particularly with regard to those measures that cut across the Medicare population and those under 65.

Furthermore, the amendment asks GAO to focus in particular on PQRS and EHR measures as those are two significant components of the proposed value-based performance incentive program.

## Toomey-Casey Amendment #3 to the Chairman's Mark

**Title:** Preserving Access to Orphan Drugs

**Purpose:** Clarify the pharmaceutical fee exemption created in P.L. 111-148 to include drugs approved by the Food and Drug Administration (FDA) for marketing solely for rare diseases.

### **Description of Amendment:**

Congress has put in place several long-standing incentives to motivate pharmaceutical companies to pursue FDA approval for products to help individuals with rare diseases, including tax incentives. In an effort to encourage orphan drug<sup>[1]</sup> development, drafters of the PPACA fee to be paid by pharmaceutical manufacturers for the sales of brand name drugs sought to exclude orphan drugs. However, they did this by tying the exemption from the pharmaceutical fee to receipt of the Orphan Drug Tax Credit (ODTC) for that particular brand name product.

Therefore, a product could be indicated by the FDA solely for the treatment of a rare disease but still subject to the PPACA fee if it did not claim the ODTC or was ineligible to claim the ODTC. There are a variety of reasons why this may be the case. For instance, some orphan drug manufacturers eligible for the ODTC may have chosen to forego it years ago in lieu of another tax credit, such as the R&D credit. These orphan drugs would be subject to the PPACA fee. Further, not all orphan drugs qualify for the ODTC. To be eligible, an orphan drug must have an orphan designation for a rare disease. The FDA traditionally only provides designation status to the first drug to market for a rare disease. Subsequent orphan drugs that treat the same rare disease are only eligible to receive an orphan indication and will therefore be subject to the PPACA fee.

The orphan exemption from the PPACA pharmaceutical fee should consider the conditions the product treats and not just its tax status. Therefore, this amendment would clarify the law to exempt orphan drugs from the pharmaceutical fee if they have received an FDA indication solely for one or more rare diseases. If a drug were subsequently approved by the FDA for marketing for any indication other than a rare disease or condition, they would be subject to the fee.

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<sup>[1]</sup> An orphan drug treats a rare disease which afflicts 200,000 or fewer individuals in the United States. Additionally, the FDA may provide orphan drug designation for a disease that affects more than 200,000 people if U.S. sales of the drug are not expected to be sufficient to recover the costs of developing and marketing a drug for treatment of the disease.