Title II- Improving the Quality and Efficiency of Health Care
Subtitle A- National Strategy to Improve Health Care Quality

Sec. 201. National Strategy

Current Law

There are no provisions in current law that require the development of national quality priorities, strategy, strategic plans, or infrastructure (directed either at the Secretary of Health and Human Services or the Agency for Healthcare Research and Quality).

However, section 1890 of the Social Security Act requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform the following duties: 1) synthesize evidence and convene stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings; 2) provide for the endorsement of standardized health care performance measures; 3) establish and implement a process to ensure that endorsed measures are updated or retired based on new evidence; 4) promote the development of electronic health records that facilitate the collection of performance measurement data; and 5) report annually to Congress.

The National Quality Forum has been awarded this contract and recently released its first report, *Improving Healthcare Performance: Setting Priorities and Enhancing Measurement Capacity*, in fulfillment of this statutory requirement.

Section 913(b)(2) of the PHS Act requires the Agency for Healthcare Research and Quality (AHRQ) to submit to Congress an annual report on national trends in the quality of health care provided to the American people. AHRQ developed the first National Healthcare Quality Report in 2003. In addition, Section 903(a)(6) of the PHS Act requires AHRQ to annually submit to Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations.

Proposed Law

This proposal would require the Secretary, through a new Part S, Section 399HH under Title III of the Public Health Service Act (PHS Act), to establish a national strategy for healthcare quality improvement. Specifically, it would require the Secretary to establish a national strategy to improve the delivery of health care services, outcomes and population health and to identify national priorities for quality improvement in developing a national strategy. The Secretary would also be required to periodically (at least triennially) update the national strategy and transmit the national strategy and updates to relevant Committees of Congress.

The national priorities would have to: 1) address health care provided to patients with high-cost chronic diseases; 2) improve the design, development, demonstration, dissemination and adoption of infrastructure and methodologies and strategies for quality improvement in the delivery of health care services that represent best practices to improve patient safety, preventable admissions and readmissions, and health care-associated infections; 3) have the greatest potential for improving health outcomes, efficiency, and patient-centeredness of care; 4) reduce health disparities; 5) address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggregation techniques; 6) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality of patient care; 7) improve Federal payment policy to emphasize quality; 8) enhance the use of health care data to improve quality, transparency, and outcomes; and 9) address other areas as determined by the Secretary.

In addition, this proposal would require the Secretary to create a comprehensive strategic plan as part of the national strategy to achieve the national priorities for quality improvement. This would include addressing, at a minimum: 1) coordination among agencies within the Department; 2) agency-specific strategic plans to achieve national priorities; 3) establishing annual benchmarks for each relevant agency to achieve national priorities; 4) a process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan; 5) using common incentives among public and private payers with regard to quality and patient safety efforts; and 6) incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (P.L. 111-5).

The Secretary would also be required to publish an annual national health care quality report card and create a website to make public the national priorities, agency-specific strategic plans, the annual national health care quality report card, and other information the Secretary deemed appropriate. The annual national health care quality report card would include: 1) the considerations for national priorities; 2) an analysis of the progress of the agency-specific strategic plans in achieving the national priorities and any gaps in such strategic plans; 3) the extent to which private sector strategies have informed Federal quality improvement efforts; and 4) a summary of consumer and provider feedback regarding quality improvement practices.

Finally, this proposal would require all relevant agencies within the Department of Health and Human Services to review the statutory authority, regulations, policies, and procedures of such agency in order to determine if there are any deficiencies that prohibit full compliance with this title. Agencies would be required to submit a proposal to the Secretary outlining the measures that may be necessary to bring the authority, regulations, policies, and procedures of the agency into conformity with the intent, purposes and provisions of this title.

Sec. 202. Interagency Working Group on Health Care Quality

Current Law

No provisions.

Proposed Law

This proposal would require the President to convene a working group to be known as the Interagency Working Group on Health Care Quality. The goals of this group would include achieving the following: 1) collaboration, cooperation and consultation between Federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities indentified in Section 399HH; and 2) avoidance of duplication of quality improvement efforts and a streamlined process for quality reporting and compliance requirements.

The Working Group would be required to include senior level representatives of the Department of Health and Human Services, the Department of Labor, the United States Office of Personnel Management, the Department of Defense, the Department of Education, the Department of Veterans Affairs, and any other Federal agencies and department with activities relating to improving health care quality and safety, as determined by the President. The Secretary of Health and Human Services would serve as the Chair, and Member of the Working Group would serve as Vice Chair, on a rotating basis.

Not later than December 10, 2010, and annually after that, the Working Group would be required to submit a report describing the progress and recommendations of the Group to relevant Committees of Congress and shall make this report publicly available on a website.

Sec. 203. Quality Measure Development

Current Law

The Agency for Healthcare Research and Quality (AHRQ) has significant existing statutory authorities with respect to the development of quality measures. Specifically, the Agency's mission, among other things, is to promote healthcare quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality (Sec. 901 of the PHS Act).

Section 912 of the PHS Act requires AHRQ to provide support for public and private efforts to improve healthcare quality, and that the role of the Agency shall specifically include the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes and the compilation and dissemination of health care quality measures developed in the private and public sector. To comply with this last requirement, the Agency has established the National Quality Measures Clearinghouse, an online resource that compiles and catalogues quality measures.

Finally, Section 917 of the PHS Act requires AHRQ to coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

Section 1890 of the Social Security Act requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform the following duties: 1) synthesize evidence and convene stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings; 2) provide for the endorsement of standardized health care performance measures; 3) establish and implement a process to ensure that endorsed measures are updated or retired based on new evidence; 4) promote the development of electronic health records that facilitate the collection of performance measurement data; and 5) report annually to Congress.

The National Quality Forum has been awarded this contract and recently released its first report, *Improving Healthcare Performance: Setting Priorities and Enhancing Measurement Capacity*, in fulfillment of this statutory requirement.

Proposed Law

This proposal would add a new Part D under Title IX of the PHS Act entitled Health Care Quality Improvement, Subpart I- Quality Measure Development.

For purposes of this subpart, quality measure would be defined as "a standard for measuring the performance and improvement of population health or of health plans, providers or services, and other clinicians in the delivery of health care services."

This proposal would direct the Director of AHRQ to identify, not less often than biennially, gaps where no quality measures exist or where existing measures need improvement, updating or expansion. The Director would be required to make a report on any gaps identified, and the process used to identify the gaps, available to the public on a website.

This provision would require the Director to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding quality measures in areas identified as gaps areas. The Director would be required to give priority to the development of quality measures that allow the assessment of 1) health outcomes and functional status of patients; 2) the continuity, management, and coordination of health care and care transitions across the continuum of providers; 3) patient, caregiver, and authorized representative experience, quality and relevance of information provided to patients, caregivers, and authorized representatives to inform decision making; 4) the safety, effectiveness, and timeliness of care; 5) health disparities; 6) the appropriate use of health care resources and services or 7) the use of innovative strategies and methodologies.

To be eligible for grants or awards under this section, entities would have to 1) have demonstrated expertise and capacity in measure development and evaluation; 2) have

adopted procedures to include the views of those whose performance would be assessed by the measure and the views of other parties who also would use the quality measures in the development process; 3) collaborate with a qualified consensus-based entity, as practicable, and the Secretary to that measures will meet the requirements to be considered for endorsement by such qualified consensus-based entity; 4) have transparent policies regarding conflicts of interest; and 5) submit an application according to requirements of the Secretary.

An entity receiving funds under this section would be required to use the funds to develop quality measures that meet the following requirements: 1) such measures build upon measures developed under section 1139A of the Social Security Act; 2) to the extent practicable, data on measures is able to be collected using HIT; 3) each measure is free of charge to users; and 4) each quality measures is publicly available on a website.

The funds under this section would be able to be used by the Director to update and test quality measures endorsed by a qualified consensus-based entity.

An appropriation of $75,000,000 per year from FY2010 through FY2014 would be authorized.

Sec. 204. Quality Measure Endorsement; Public Reporting; Data Collection.

Current Law

Section 1890 of the Social Security Act requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform the following duties: 1) synthesize evidence and convene stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings; 2) provide for the endorsement of standardized health care performance measures; 3) establish and implement a process to ensure that endorsed measures are updated or retired based on new evidence; 4) promote the development of electronic health records that facilitate the collection of performance measurement data; and 5) report annually to Congress.

The National Quality Forum has been awarded this contract and recently released its first report, *Improving Healthcare Performance: Setting Priorities and Enhancing Measurement Capacity*, in fulfillment of this statutory requirement.

With respect to public reporting of quality information, according to 1886(b)(3)(B)(viii)(VII) of the Social Security Act, the Secretary must establish procedures for making hospital quality data reported pursuant to CMS's Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program available to the public, and these procedures must ensure that a hospital has the opportunity to review the data prior to such data being made public.

Also according to section 1886(b)(3)(B)(viii)(VII) of the Social Security Act, the Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

Currently, individual hospital performance on specific quality measures and on certain conditions is available on CMS's Internet website, Hospital Compare.

Proposed Law

This section would amend Title III of the PHS Act by adding three new sections: 1) 399JJ- Quality Measure Endorsement; 2) 399KK: Public Reporting of Performance Information; and 3) 399LL: Evaluation of Data Collection Process for Quality Measurement.

Section 399JJ

Section 399JJ would define the following terms: 1) qualified consensus-based entity: means an entity with a contract with the Secretary under section 1890 of the Social Security Act; 2) quality measure: means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services; and 3) multi-stakeholder group: means a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the sue of such quality measure.

A qualified consensus-based entity would be permitted to receive a grant or contract to: 1) make recommendations to the Secretary for national priorities for performance improvement; 2) identify gaps in endorsed quality measures as specified; 3) identify and endorse quality measures, including measures that address gaps; 4) update endorsed measures; 5) make endorsed measures publicly available and have a plan for wide-spread dissemination; and 6) transmit endorsed measures to the Secretary.

A qualified consensus-based entity that received a grant under this section would be required to provide a report to the Secretary (no less than annually) 1) of where gaps exist and where measures are unavailable or inadequate to identify or address such gaps and 2) regarding areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy. A qualified consensus-based entity that receives a grant shall provide a report to the Secretary (no less than annually) regarding the economic and quality impact of the use of endorsed measures.

A qualified consensus-based entity that receives a grant under this section would be required to evaluate the evidence and convene multi-stakeholder groups to make recommendations for national priorities for performance improvement not less frequently than triennially. In making these recommendations, the qualified consensus-based entity

would be required to ensure that priority is given to areas in the delivery of health care services for all populations, including children and other vulnerable populations that 1) address the health care provided to patients with prevalent, high-cost chronic diseases; 2) improve the design, development, demonstration, dissemination and adoption of infrastructure and methodologies and strategies for quality improvement in the delivery of health care services that represent best practices to improve patient safety, preventable admissions and readmissions, and health care-associated infections; 3) have the greatest potential for improving health outcomes, efficiency, and patient-centeredness of care; 4) reduce health disparities; 5) address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggregation techniques; 6) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality of patient care; and 8) address the appropriate use of health care technology.

This process would be required to be open and transparent, and the selection of organizations participating in the multi-stakeholder groups shall include provisions for public comment on and public nomination of members.

A qualified consensus-based entity that receives a grant under this section would be required to convene multi-stakeholder groups to provide guidance on the selection of individual or composite measures, for use in reporting performance information to the public or for use in Federal health programs from among 1) measures that have been endorsed by the qualified consensus-based entity (under Section 1890(b) of the SSA); and 2) measures that have not been considered for endorsement by the qualified consensus-based entity but are used or proposed to be used by the Secretary under laws that require the collection or reporting of quality measures. The guidance of the multi-stakeholder groups would be required to be transmitted to the Secretary by the qualified consensus-based entity. This process would be required to be open and transparent, and the selection of organizations participating in the multi-stakeholder groups would be required to include provisions for public comment on and public nomination of members.

Under this section, the Secretary would be permitted to make a determination under regulation or otherwise to use a quality measure that has been endorsed by the qualified consensus-based entity (under Section 1890(b) of the SSA) only after taking into account the guidance of multi-stakeholder groups, as described above. The Secretary would be permitted to make a determination to use a quality measure that has not been endorsed provided that the Secretary 1) transmits the measure to the qualified consensus-based entity for consideration for endorsement and for the multi-stakeholder consultation process to provide guidance on the selection of individual or composite measures, for use in reporting performance information to the public or for use in Federal health programs; 2) publishes in the Federal Register the rationale for the use of the measures; and 3) phases out use of the measure upon a decision of the qualified consensus-based entity not to endorse the measure, contingent on the availability of an adequate alternative endorsed measure. If there is no adequate alternative, the Secretary would be required to support the development of such an alternative measure.

This section would require that the Secretary establish a process to notify the qualified consensus-based entity when its recommendations regarding quality measures would have to be submitted to the Secretary for consideration in development of a regulation. The notification would be required to occur at least 120 days prior to the date that recommendations were due.

In publishing specified regulations, the Secretary would be required to include a description of each recommendation of the qualified consensus-based entity and the Secretary's responses to each recommendation. Specified regulation would be defined to mean a notice of proposed rulemaking to implement the collection or reporting of data on quality measures. This subsection would apply with respect to determinations or requirements by the Secretary for the use of quality measures made on or after the date of enactment of the Affordable Health Choices Act.

This section would also require the Secretary to review quality measures used by the Secretary not less than once every three years, to determine whether to maintain the measure or phase it out. In conducting the review, the Secretary would be required to 1) seek to avoid duplication of measures; and 2) take into consideration current innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices for such quality improvement and measures endorsed by a qualified consensus-based entity since the previous review.

The Secretary would also be required to establish a process, as specified, for disseminating quality measures used by the Secretary.

An appropriation of $50,000,000 for each year from FY2010 to FY2014 would be authorized.

Section 399KK

This section would require the Secretary to implement, within 5 years of enactment, a system for the reporting on quality measures that protect patient privacy, and where appropriate: 1) assess health outcomes and functional status of patients; 2) assess the continuity and coordination of care and care transitions as specified; 3) assess patient experience and patient caregiver and family engagement; 4) assess the safety, effectiveness, and timeliness of care; and 5) assess health disparities as specified. These measures would be required to be: 1) risk-adjusted as specified; 2) valid, reliable, evidence-based, feasible to collect, and actionable by providers, payers, and consumers, as appropriate; 3) minimize the burden of collection and reporting such measures; and 4) be consistent with the national strategy.

This section would require the Secretary to make available to the public performance information summarizing data on quality measures collected under this section through a series of standardized websites, tailored as specified. Each website would be required to be designed to make the use and navigation of it readily available to individuals assessing it. Performance information on these websites would be required to be made available by

clinical condition and where appropriate be provider-specific to meet the needs of patients with different clinical conditions. The Secretary would be required to carry out the development of performance websites in collaboration with a qualified consensus-based entity to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting websites. The qualified consensus-based entity would be required to convene specified multi-stakeholder groups to review the design and format of each website and to transmit the views of such groups to the Secretary.

Section 399LL

This section would require the Comptroller General of the United States to conduct periodic evaluations of the implementation of the data collection processes for quality measures to be used by the Secretary.

In carrying out the evaluation, the Comptroller General would be required to determine 1) whether the system for the collection of data for quality measures provides for validation of data as relevant, fair, and scientifically credible; 2) whether data collection efforts use the most efficient and cost-effective means as specified; 3) whether standards under the system provide for an opportunity for physicians and other clinicians to review and correct findings; 4) the extent to which measures a) assess health outcomes as specified; b) assess the continuity and coordination of care and care transitions as specified; c) assess patient experience and patient caregiver and family engagement; d) assess the safety, effectiveness, and timeliness of care; e) assess health disparities as specified; f) address the appropriate use of health care resources and services; g) are designed to be collected as part of health information technologies as specified; h) result in direct or indirect costs to users of such measures; and i) provide utility to both the care of individuals and the management of population health.

The Comptroller General would be required to submit reports to Congress and the Secretary containing a description of the findings and conclusion of the results of each such evaluation.

Sec. 205. Collection and Analysis of Quality Measure Data.

Current Law

No provisions regarding collection and analysis of quality measure data.

Section 3002 of the PHS Act established an HIT Policy Committee to make policy recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure. The duties of the Committee are specified at section 3002(b)(2)(B).

Proposed Law

This section would amend Part S of Title III of the PHS Act by adding Section 399MM, Collection and Analysis of Quality Measure Data.

This section would require the Secretary to establish a process to collect, and validate, aggregate data on quality measures to facilitate public reporting. This process would be required to: 1) be focused, scientifically sound, and practicable to implement; 2) where practicable, be incorporated into health information technology to allow collection of measures at the point of care; and 3) integrate data from public sources and privates sources.

This section would require the Secretary to collect, validate and aggregate data on quality measures from providers receiving funds under this Act. The Secretary would be permitted to award grants or contracts for terms of up to 5 years to eligible entities to collect, validate and aggregate data on quality measures. Eligible entities would be required to: 1) be a public or private entity, or an entity that administers a disease or population registry; 2) provide timely information to providers regarding their performance on quality measures relative to the performance of other providers; 3) make de-identified data on quality measures available to the public in accordance with the process established by the Secretary (and described above); 4) collaborate with the State health information technology entities and exchanges; 5) meet the standards for data aggregators established by the Secretary in this section; and 6) submit to the Secretary an application containing an assurance that the entity will meet each standard and such other information as the Secretary may require.

This section would require the Secretary to establish standards for data aggregators that would be required to be met by each entity that receives a grant or contract under this subsection, including standards on the protection of privacy and security of patient data.

An appropriation of $75,000,000 each year from FY2010 to FY2014 would be authorized.

This section would expand the duties of the HIT Policy Committee to include the use of certified electronic health records to collect and report quality measures accepted by the Secretary.

Subtitle B- Health Care Quality Improvements

Sec. 211. Health Care Delivery System Research; Quality Improvement Technical Assistance

Current Law

Title IX, section 901(a)(1)(G) of the PHS Act, provides AHRQ with broad general authorities in the area of research that develops and presents scientific evidence regarding all aspects of health care, including ways in which patients, consumers, purchasers, and

practitioners acquire new information about best practices and health benefits and the determinants and impact of their use of this information.

In addition, section 902(c) provides the Director with the authority to provide financial assistance to assist in meeting the costs of planning and establishing new centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis.

Title IX, section 934, provides the Agency with broad authority to disseminate results of research, demonstration projects, and evaluations conducted or supported under the title.

Under section 301 of the PHS Act, the Secretary has general authority to conduct and promote the coordination of research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases impacting individuals and to award grants for public health purposes.

Proposed Law

This section would amend the PHS Act by adding section 933, Health Care Quality Improvement Programs, to Part D of Title IX. This section would have the following purposes: 1) enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care quality, safety and value; and 2) ensure that the Director is accountable for implementing a model to pursue such research in a collaborative manner with other related Federal agencies.

This section would establish the Patient Safety Research Center in the Agency for Healthcare Research and Quality. The general functions of this Center would include: 1) carrying out its functions using research from a variety of disciplines; 2) conducting or supporting activities identified in the subsection about the Center's purposes, and with respect to best practices for quality improvement practices in the delivery of health care services, and that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors, and facilitate adoption of improved workflow; 3) identifying providers that delivery consistently high-quality, efficient health care services and employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings; 4) assessing research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery; 5) finding ways to translate such information rapidly and effectively; 6) creating strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variation s in the delivery of health care; 7) identifying, measuring and improving organizational, human or other factors that contribute to the success of specific quality improvement strategies; 8) providing for the development of best practices in the delivery of health care services as specified; 9) providing for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services; and 10)

building capacity at the State and community level to lead quality and safety efforts through education, training and mentoring programs.

The Center would be required to support research on health care delivery system improvement and the development of tools to facilitate the adoption of best practices that improve the quality, safety and efficiency of health care delivery services. This could include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality. Recipient of funding would be permitted to include national, State, multi-State, or multi-site quality improvement networks.

The research conducted by the Center would be required to: 1) address specified national priorities; 2) identify areas in which evidence is insufficient to identify strategies and methodologies; 3) address concerns identified by health care institutions and providers and communicated through the Center; 4) reduce preventable morbidity, mortality, and associated costs by building capacity for patient safety research; 5) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of healthcare; 6) be designed to help improve health care quality and is tested in practice-based settings; 7) allow communication of research findings and translate evidence into specified practice recommendations that are adaptable to a variety of settings; 8) expand demonstration projects for improving the quality of children's health care and the use of health information technology; 9) identify and mitigate hazards by analyzing events reported to patient safety reporting systems and organizations and using the results of such analyses to develop scientific methods of response to such events; 10) include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery; and 11) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

This section would require the Director to make the research findings of the Center available to the public through multiple media and appropriate formats. The Secretary would be required to ensure that research findings and results generated by the Center are shared with the Office of the National Coordinator of Health Information Technology, and used as specified. In addition, the Director would be required to identify and regularly update a list of processes or systems on which to focus research and dissemination activities of the Center, taking into account: 1) cost to Federal health programs; 2) consumer assessment of health care experience; 3) provider assessment of such processes or systems and opportunities to minimize distress and injury to the health care workforce; 4) potential impact of such processes or systems on health status and function of patients, including vulnerable populations; 5) specified areas of insufficient evidence; and 6) the evolution of meaningful use of health information technology.

An appropriation of $20,000,000 each year for fiscal years 2010 through 2014 would be authorized.

Title IX, Part D of the PHS Act, would be amended to add Section 934, Quality Improvement Technical Assistance and Implementation.

This section would require the Director, through the Center, to award: 1) technical assistance grants or contracts to eligible entities to provide technical support to institutions that deliver health care so that such institutions understand, adapt, and implement the models and practices identified in the research conducted by the Center; and 2) implementation grants or contracts to eligible entities to implement the models and practices developed by recipients of the grants described in 1).

To be eligible to receive a technical assistance grant or contract, an entity 1) could be a provider, provider association, professional society, health care worker organization, quality improvement organization, patient safety organization, local quality improvement collaborative, the Joint Commission, academic health center, university physician-based research network, specified primary care extension program, or any other entity identified by the Secretary; and 2) would be required to have demonstrated expertise in providing information and support to health care providers regarding quality improvement. In order to receive a technical assistance grant or contract, an eligible entity would be required to submit an application to the Secretary, at such time in such manner as the Secretary requires, containing a plan for sustainable business model, as specified, and such other information as the Director may require.

To be eligible to receive an implementation grant or contract, an entity: 1) could be a hospital or other provider or consortium of providers; and 2) would be required to have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement. In order to receive an implementation grant or contract, an eligible entity would be required to submit an application to the Secretary at such time, in such manner as the Secretary requires, and containing a plan for implementation of a model or practice identified in the research conducted by the Center, as specified, and such other information as the Director may require.

This section would prohibit the Director from awarding a grant or contract to an entity unless the entity agrees that it will make available non-Federal contributions in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal funds could be provided directly or through donations from public or private entities and may be in cash or in-kind, as specified. This section would also require the Director to evaluate the performance of each entity, which would have to include: 1) the success of such entity in achieving the implementation of the models and practices identified in the research conducted by the Center in section 933; 2) the perception of the health care institutions and providers assisted by such entity; and 3) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity. The decision about whether to renew a grant or contract with such entity would be required to be based on the outcome of this evaluation.

This section also requires entities receiving grants or contracts to coordinate with health information technology regional extension centers and the primary care extension program established under section 399T.

Sec. 212. Grants to establish community health teams to support a medical home model

Current Law

Section 204 of the Tax Relief and Health Care Act of 2006 (PL 109-432) mandated a demonstration in up to 8 States to provide targeted, accessible, continuous and coordinated care to Medicare beneficiaries with chronic or prolonged illnesses requiring regular medical monitoring, advising or treatment. This model is commonly referred to as a medical home. Section 133 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, PL 110-275) allowed the Secretary to expand the demonstration project as appropriate, subject to certain limitations.

Proposed Law

This section would direct the Secretary of Health and Human Services (Secretary) to establish a grant program to establish health teams to provide support to primary care providers and provide capitated payments to primary care providers determined by the Secretary. The section sets forth what the requirements would be for grantees, health teams, and primary care providers, as described below.

An eligible grantee would have to be a State (or designee); submit a specified plan for financial sustainability, as well as a plan for incorporating prevention initiatives, patient education, and care management resources into care delivery; ensure that the health team that is established includes a multidisciplinary interprofessional team of providers as specified; and submit an application to the Secretary at such time and in such manner as the Secretary may require. Grant recipients would be required to submit to the Secretary as requested a report that describes and evaluates health team activities.

A health team established pursuant to the grant would be required to (1) establish contractual agreements with primary care providers to provide support services; (2) support medical homes as defined in the section; (3) collaborate with specified resources to coordinate specified care for patients; (4) develop plans as specified that integrate preventative services for patients; (5) incorporate providers, patients, caregivers and authorized representatives in program design and oversight; (6) provide support necessary for local primary care providers for specified activities; (7) provide specified 24-hour care management and support during transitions in care settings; (8) serve as a liaison to community prevention and treatment programs; (9) demonstrate a capacity to meet health information technology requirements as specified; and (10) where applicable, report to the Secretary on information quality measures as specified.

Primary care providers who contracted with care teams would be required to provide care plans for patient participants, provide access to participant health records and primary care practices, and meet regularly with the care team to ensure integration of care.

Sec. 213. Grants to implement medication management services in treatment of chronic disease

Current Law
Nothing in the PHS Act is strictly applicable, although the Secretary could address the issue using general authorities under Title III. Some mechanisms related to medication management (MTM) exist in Medicare Part D and in Medicaid as described below.

The Medicare Modernization Act of 2003 (MMA) under title 42 CFR Part 423, Subpart D, establishes the requirements that Part D Plans must meet with regard to cost control and quality improvement including requirements for MTM Programs (MTMPs). Under section 423.153(d), a Medicare Part D Sponsor must establish a MTMP that (1) is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use; (2) is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries; (3) is developed in cooperation with licensed and practicing pharmacists and physicians; (4) may be furnished by pharmacists or other qualified providers; (5) may distinguish between services in ambulatory and institutional settings; and (6) describes the resources and time required to implement the program if using outside personnel and establishes the fees for pharmacists or others.

The MMA provided a number of examples of multiple chronic conditions that could be targeted for MTMP, including diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. Part D Plans have significant flexibility however, in determining which targeted populations are appropriate for MTM. Plans also have flexibility to determine other components of their MTMP including method of enrollment, interventions, provider of MTM services, and outcomes.

In response to the MMA's requirement that Part D plans have a MTM program, CMS conducted an investigative study to understand the attributes and features of MTM models currently being used in the public and private sectors. The study, which was completed in July 2008, revealed that it is too soon to tell how the various models contribute to clinical outcomes.

In Medicaid, Section 6081 of the Deficit Reduction Act (DRA) authorizes grant funds to States for Transformation Grants aimed at the adoption of innovative methods to improve effectiveness and efficiency in providing medical assistance under Medicaid. One permissible use of such funds is for implementation of a medication risk management program as part of a drug use review program under section 1927(g) (SSA section 1903(z)).

A medication risk management program is one for targeted beneficiaries that ensures, by means of specified elements, that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. ‘‘Targeted beneficiaries’’ means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals

with behavioral disorders or multiple chronic diseases who are taking multiple medications.

Proposed Law

This section would insert a new section 935 into PHS Act Title IX following section 936 [sic.]. The new section would require the Secretary, acting through the Patient Safety Research Center (Center) established in section 933, to commence by May 1, 2010 a program to provide grants to implement medication management (MTM) services as specified. The section sets forth requirements for grantees, MTM services for targeted individuals, defining who is considered a targeted individual, and the Secretary's associated responsibilities, as described below.

To be eligible to receive a grant, entities would have to provide a setting appropriate for MTM services; submit to the Secretary a plan for achieving long term financial sustainability, a plan for meeting specified requirements for MTM services to targeted individuals and, where appropriate a plan for coordinating MTM services through local community health teams as specified; and submit other information if required by the Secretary.

MTM services to targeted individuals provided with the assistance of a grant would have to include, as specified, performing or obtaining assessments of patients' health and functional status; formulating an MTM plan; administering appropriate MTM services; monitoring and evaluating patient response to therapy; performing reviews of medication-related problems initially, quarterly and as needed; documenting the care delivered and communicating essential aspects to appropriate care providers; providing education and training to enhance the appropriate use of medications; providing information and other specified support to enhance patient adherence to therapy regimes; coordinating and integrating MTM services in broader health care management; and other patient care services as permitted by Federal law.

Targeted individuals would include individuals who take 4 or more prescribed medications; take 'high risk medications'; have two or more chronic diseases; or have undergone a transition of care or other factors that are likely to create a high risk of medication-related problems.

The Secretary would be required to design and implement MTM services provided under grants in consultation with specified experts, and determine whether it is possible to incorporate improvement concepts in use in other Federal programs that have implemented MTM services. The Secretary would also be required to submit to relevant Congressional committees a report assessing and evaluating specified aspects of the program. The Secretary would be permitted, through the specified quality measure development program, to award grants or contracts for the development of performance measures that assess the use and effectiveness of MTM services.

Sec. 214. Design and Implementation of Regionalized Systems for Emergency Care

Current Law

The Trauma Care Systems Planning and Development Act of 1990 (PL 101-590) created Title XII of the PHS Act to improve emergency medical services and trauma care. As amended, Title XII includes a number of grant programs through a grant program available to State Emergency Medical Services (EMS) offices to improve the trauma care component of the State's EMS plan; a grant program to improve rural EMS care; and discretionary grants for research, evaluation, and demonstration projects for special EMS/trauma initiatives. PL 101-590 also directed the Health Resources and Services Administration (HRSA) to develop a model trauma care systems plan, which was issued in 1992. In 2001, HRSA established the Trauma-EMS Systems Program in accordance with Title XII. This program was last funded in FY2005 at $3.4 million.

Title XII of the PHS Act has been subsequently amended, most recently by the Trauma Care Systems Planning and Development Act of 2007 (PL 110-23). Among other things, the legislation modified the requirements placed on a State's plan for emergency medical services, including requirements with respect to the collection and reporting of data on the extent of trauma care provided. The Secretary was also required to update the 1992 model plan for designation of trauma centers and for triage, transfer, and transportation polices. HRSA's model plan is guidance that may be adopted by States after appropriate consultation and public hearings. Generally, PL 110-23 directs the Secretary not make certain payments authorized by Title XII unless the State has adopted specified standards as included in the model plan.

HRSA helps fund the National EMS Information System (NEMIS), a project to create a national EMS database containing standardized information from State and local EMS agencies across the nation. Since the 1970s, the need for EMS information systems and databases has been well established, and many statewide data systems have been created. However, these EMS systems vary in their ability to collect patient and systems data and allow analysis at a local, State, and national level. The NEMSIS project was developed to help States collect more standardized elements and eventually submit the data to a national database. The National Trauma Data Bank (NTDB) is a national registry of trauma incident data submitted by U.S. trauma centers. The NTDB creates and distributes datasets that can be used by researchers. Data are aggregated and used to produce annual reports, hospital benchmark reports, and data quality reports.

Proposed Law

The proposal would amend PHS Act section 1203, which provides grants to States and localities to improve access to and enhance the development of trauma care systems, by modifying the section heading to read "Competitive Grants for Trauma Systems for the Improvement of Trauma Care" and by transferring administration of the program from HRSA to the Assistant Secretary for Preparedness and Response.

The proposal would further amend the PHS Act by adding a new section 1204 authorizing the Secretary, acting through the Assistance Secretary for Preparedness and Response, to award no less than four multiyear contracts or competitive grants for pilot projects to improve regional coordination of emergency services, including acute, prehospital, and trauma care. Entities eligible for funding include individual States, or partnerships of one or more States and one or more local governments. Funding would be awarded to eligible entities that propose a pilot project to design, implement, and evaluate an emergency medical and trauma system that: (1) coordinates with health and emergency care providers throughout the region as specified; (2) includes a mechanism to ensure the patient is taken to the medically appropriate facility in a timely manner; (3) allows for the tracking of prehospital and hospital resources (e.g., inpatient bed and emergency department capacity) and the coordination of such tracking with regional communications and hospital destination decisions; and (4) includes a region-wide data management system that reports data to the NEMIS, the NTDB, and Federal and State databanks and registries, and that contains sufficient information to evaluate key elements of emergency response and care, and relevant health outcomes.

A grant application would have to include an assurance that the proposed system: (1) had been coordinated with the State Office of Emergency Medical Services (or its equivalent); (2) coordinated triage, treatment, and interfacility transport throughout the region; and (3) included a regional medical direction, patient tracking, and resource allocation system supporting emergency care and surge capacity, among other things. Grantees would be required to provide matching funds (in cash or in kind) of at least $1 for every $3 of federal funding. Funding priority would be given to entities serving medically underserved areas, as defined in PHS Act section 330. Within 90 days of completing a pilot project, the grantee would be required to submit to the Secretary a detailed evaluation of the program's characteristics and impact. The Secretary would be required, as appropriate, to disseminate that information to the public and to Congress.

In addition, the proposal would authorize to be appropriated for Title XII Parts A and B trauma care grant programs $24 million for each of FY2010 through FY2014, and would transfer authority for administering those grants and related authorities to the Assistant Secretary for Preparedness and Response.

Finally, the proposal would amend the PHS Act by adding a new section 498D directing the Secretary to expand and accelerate research on emergency medical care systems and emergency medicine, including pediatric emergency medical care. The Secretary would also be required to support research on the economic impact of coordinated emergency care systems. The proposal would authorize to be appropriated such sums as may be necessary for each of FY2010 through FY2014 to carry out this section.

Sec. 215. Trauma Care Centers and Service Availability

Current Law

Section 1241 of the PHS Act authorizes grants to provide the operating costs of trauma centers that have incurred substantial uncompensated costs providing care in geographic areas with a significant incidence of violence arising from the illicit trafficking of drugs.

In 1976, the American College of Surgeons (ASC) Committee on Trauma developed criteria for categorizing hospitals according to the level of trauma care available. These designations range from Level 1 through Level IV, depending on the clinical capacities, facility resources, and services of the center. States may use these guidelines as a basis for designating or certifying hospitals as trauma centers, with modifications as deemed necessary. In certain States without formal trauma systems, hospitals have voluntarily sought certification from ASC.

Proposed Law

Section 1241 of the PHS Act would be replaced to revise provisions governing grants to trauma centers. The Secretary would be required to establish three programs to award grants to qualified public, nonprofit, Indian Health Service, Indian tribal, and urban Indian trauma centers to (1) assist in defraying substantial uncompensated care costs; (2) to further the core missions of such centers, including addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, and essential personnel and other fixed costs; and (3) to provide emergency relief to ensure availability of trauma services.

A trauma center would not be eligible for such a grant unless it is a participant in a trauma system that substantially complies with the trauma care component of the State plan for the provision of EMS. This requirement would not apply to trauma centers that are located in States with no trauma care system.

The Secretary would award the newly structured substantial uncompensated care grants to qualifying trauma centers that meet one of the criteria in one of the following three categories: The criteria for **Category A** would be (1) at least 50% of the visits in the emergency department in which the trauma center is located were charity or self-pay patients; or (2) at least 70% of the visits in the emergency department were provided to Medicaid, charity, and self pay patients. The criteria for **Category B** would be (1) at least 35% of the visits in the emergency department in which the trauma center is located were charity or self-pay patients; or (2) at least 50% of the visits in the emergency department were provided to Medicaid, charity, and self pay patients. The criteria for **Category C** would be (1) at least 20% of the visits in the emergency department in which the trauma center is located were charity or self-pay patients; or (2) at least 30% of the visits in the emergency department were provided to Medicaid, charity, and self pay patients. Alternatively, the a trauma center may be awarded a substantial uncompensated care grant if it qualifies for funds under a Low Income Pool or Safety Net Pool established under a Medicaid waiver pursuant to section 1115 of the Social Security Act.

Subject to certain requirements, Category A trauma centers would be eligible for grants up to 100% of their uncompensated care costs; Category B trauma centers would be

eligible for not more than 75% of their uncompensated care costs; and Category C trauma centers would be eligible for not more than 50% of their uncompensated care costs. With respect to the amount appropriated for substantial uncompensated care grants in a fiscal year, 50% would be available to Category A grantees; 35% would be available to Category B grantees and 15% would be available to Category C grantees.

The term, "uncompensated care costs" would be defined as unreimbursed costs from serving self-pay, charity, or Medicaid patients, without regard to Medicaid disproportionate share hospital (DSH) payments, attributed to emergency and trauma care, including the costs related to subsequent inpatient admissions to the hospital.

With respect to the new core mission grants, the Secretary would be required to allocate specified percentages of funds allocated for such awards to certain types of trauma centers providing specified services. Specifically, the Secretary would be required to reserve 25% of the allocated amount for core mission awards for Level III and Level IV trauma centers and 25% of the allocated amount for large urban Level I and II trauma centers. To qualify, Level I and II trauma centers would have to (1) have at least 1 graduate medical education fellowship in trauma or trauma related specialties for which demand exceeds supply; and (2) provide either annual uncompensated care costs in excess of $10 million; or provide at least 20% of emergency department visits to charity, self pay or Medicaid patients, and not be eligible for substantial uncompensated care grants.

The section would establish emergency awards, and would require the Secretary to give funding preference to a trauma center in a geographic area in which the availability of trauma care has significantly decreased or will significantly decrease if the center is forced to close or downgrade services or where the growth in the demand for trauma services exceeds capacity. The Secretary would also be required to reallocate any emergency funds not obligated due to insufficient or lack of qualified applications to the significant uncompensated care award program. A trauma center would be able to receive emergency grants for three fiscal years unless the Secretary waives the time lime and authorizes an additional year of emergency grants for the center.

The section would amend PHS Act section 1243 to allow the Secretary, in awarding these three grants that would be established by 1241(a), to require a trauma center to maintain access to trauma services at comparable levels to the prior year during the grant program. Moreover, these trauma centers may be required to provide data to a national and centralized registry of trauma centers, in accordance with guidelines developed by the American College of Surgeons (ACS) and other requirements.

PHS Act section 1244 would be amended to do a number of things. It would preclude the Secretary from awarding a grant to a trauma center unless the center submits a grant application that complies with requirements established by the Secretary. It would also limit grants to three years (with a specific exception), and to $2 million per grant per fiscal year. Except as specified above (centers that receive substantial uncompensated care grants would not be eligible for the reserve funding for core mission grants), receipt

of a grant established in this provision would not preclude a trauma center from being eligible for other grants established by section 1241(a), as it would be amended.

Of the total amount appropriated for these grants in a fiscal year, 70% would be used for substantial uncompensated care grants; 20% would be used for core mission grants, and 10% would be used for emergency grants. However, if the amount appropriated for these grants in any year were to be less than $25 million, all available funding would be used for substantial uncompensated care awards. Grant funds for substantial uncompensated care awards would be distributed as specified.

Section 1245 of the PHS Act would be amended to authorize an appropriation for these grants for an additional $100 million for FY2009, and such necessary sums authorized for each fiscal year from 2010 to 2015.

Section 1246 of the PHS Act would be amended to include a definition for uncompensated care costs.

A new section 1281 would be added to Title XII of the PHS Act providing for grants to States to promote universal access to trauma care services provided by trauma centers and trauma-related physician specialties. The Secretary would provide funding to States, who would then award grants to eligible entities. Eligible entities would be required to be (1) a public or nonprofit trauma center or consortium that participates in a substantially compliant trauma system (or are located in States with no such trauma care system) that has been verified by the ACS or so designated by an appropriate State or local agency; (2) a safety net public or nonprofit trauma center that meets the requirements of substantial uncompensated care grants; or (3) a hospital in an underserved area (as defined by the State) that seeks to establish new trauma services. (Note: This requirement is A or B or C, not A and B or C). To receive a State grant, an eligible entity would be required to submit an application as required by the State.

State grants would be awarded for the following activities: (1) to support physician compensation in trauma related physician specialties where shortages exist in the region involved; priority would be given to safety net trauma centers; (2) to provide fiscal stability and cover costs related to having a service available 24 hours a day, seven days a week; priority would be given to safety net trauma centers located in urban, border and rural areas; (3) to reduce overcrowding; (4) to establish new trauma services in underserved areas: (5) to enhance collaboration between trauma centers, other hospitals and EMS personnel; (6) to make capital improvements, including providing helipad and associated safety infrastructure; (7) to enhance trauma surge capacity at specific trauma centers; (8) to expedite receipt of trauma patients transported by ground or air; and/or (9) to enhance interstate trauma center collaboration.

A State would be required to use 40% of the available funding for State grants to safety net trauma centers. A State would not be able to use more than 20% of its funding in a fiscal year for administrative costs. A State would not receive funding unless it agrees

that such funds will supplement and not supplant existing State funding for these activities.

If annual appropriations are less than $10 million in a fiscal year, the Secretary would divide funds evenly among those States that have one or more Category A trauma centers eligible for substantial uncompensated care grants. If annual appropriations are less than $20 million in a fiscal year, the Secretary would divide funds evenly among those States that have one or more Category A and Category B trauma centers eligible for substantial uncompensated care grants. If annual appropriations are less than $30 million in a fiscal year, the Secretary would divide funds evenly among those States that have one or more trauma centers eligible for substantial uncompensated care grants. If the appropriated amount were $30 million or more in a fiscal year, the Secretary would divide such funding evenly among all States. For fiscal years 2010 through 2015, $100 million would be authorized to be appropriated for State grants.

Sec. 216. Reducing and Reporting Hospital Readmissions

Current Law

No provisions.

Proposed Law

This provision would add a new section 399NN to the PHS Act in order to improve the quality and value of inpatient hospital services to (1) improve the coordination of care; and (2) appropriately reduce inefficiency and waste, such as unnecessary hospital readmissions.

Beginning in 2010, the Secretary would be required to analyze and calculate hospital-specific and national applicable readmissions rates as specified in this provision.

Beginning in 2011, the Secretary would be required to establish procedures to provide for the confidential disclosure to hospitals receiving funds under this Act of information on the hospital-specific and national applicable readmission rates, as specified in this provision.

No later than 2 years after enactment, the Secretary would be required to disclose publicly, in a form and manner determined by the Secretary, this information on the rates of applicable readmission rates and other statistical information of hospitals receiving funds under the PHS Act. No later than 180 days after enactment, the Secretary would be required to submit to Congress a report that contains: (A) a summary of the implementation of these procedures; (B) a plan for the public disclosure of this information; and (C) recommendations for such legislation or administrative action as the Secretary would determine appropriate.

The term applicable readmission would mean a readmission: (A) selected by the Secretary; (B) occurring within a time interval (the Secretary would be required to specify a time interval of not less than 7 days and not more than 30 days, between the prior discharge and applicable readmission); and (C) which would be for a condition or procedure selected according to the terms of this provision. The Secretary would be required to determine whether the term applicable readmission would include readmissions to the same hospital as the prior discharge or readmissions to any hospital.

Not later than 6 months after the date of enactment, the Secretary, in consultation with appropriate representatives of CMS and AHRQ, would be required, for each of the conditions or procedures selected, to select readmissions that meet two criteria. First, the readmissions must have been reasonably preventable by the provision of care consistent with evidence-based guidelines during the prior admission or the post discharge follow-up period; and second, they must have been for a condition or procedure related to the care provided during the prior admission or post discharge follow-up period, which includes readmissions for the following: (A) the same condition or procedure as the prior discharge; (B) an infection or other complication of care; (C) a condition or procedure indicative of a failed surgical intervention; and (D) other conditions or procedures as determined by the Secretary.

Not later than 6 months after enactment, the Secretary would be required to select at least 2 conditions or procedures which meet the following requirements: (A) such conditions or procedures would have a high volume; and (B) for the time interval specified by the Secretary (as described above), such conditions or procedures would have a relatively high rate of occurrence of subsequent readmissions (as specified above), as compared to all other conditions or procedures. The Secretary would be required to expand the list of readmission conditions to include at least 8 conditions with the highest volume and highest rate of readmissions.

Quality Improvement Program for Hospitals with a High Severity Adjusted Readmission Rate

Not later than 2 years after the date of enactment, the Secretary would be required to establish a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations. Eligible hospitals would be defined as a hospital which the Secretary would determine (based on the most recent available historical data) has a severity adjusted readmission rate for the selected conditions among the highest 25 percent of all hospitals nationally. The Secretary would be required to utilize appropriate risk adjustment measures to determine eligible hospitals. Eligible hospitals and patient safety organizations working with those hospitals would be required to report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

The Comptroller General of the United States would be required to conduct a study on the impact of section 399NN (which would be comprised of the provisions added by the

bill's section 216 that are discussed above) on care furnished to consumers, expenditures under Federal health programs, and the cost and quality of care furnished by hospitals. Not later than January 1, 2013, the Comptroller General would be required to submit to Congress a report on this study together with recommendations for such legislation and administrative action as the Comptroller General would determine appropriate.

Sec. 217. Program to Facilitate Shared Decision-Making

Current Law

No provisions.

Proposed Law

The proposal would amend the PHS Act by adding a new section 936 to facilitate shared decision-making between patients and caregivers (or authorized representatives) and their clinicians, by engaging the patient or individual acting on their behalf in clinical decision-making, providing information on trade-offs among treatment options, and incorporating patient preferences and values into the medical plan.

As soon as practicable after enactment of this Act, the Secretary would be required to enter into a renewable 18-month contract with the qualified consensus-based organization created under PHS Act section 399JJ (as added by this Act) to develop and identify standards for patient decision aids for preference sensitive care and to review patient decision aids and develop a certification process for determining whether patient decision aids meet those standards. A patient decision aid is defined as an educational tool to help patients understand and communicate their beliefs and preferences related to their treatment options and to decide which treatment is best for them based on scientific evidence, circumstances, beliefs, and preferences. Preference sensitive care is defined as medical care for which the clinical evidence does not clearly support one treatment option, such that the appropriate course of treatment depends on the values or preferences of the patient regarding the benefits, harms and scientific evidence for each treatment option.

The Secretary, acting through the AHRQ Director and in coordination with other relevant agencies, would be required to award grants or contracts: (1) to develop, update and produce patient decision aids for preference sensitive care to assist health care providers in educating patients about the relative safety, cost, and effectiveness of different care options; (2) to test such materials to ensure they are balanced and evidence-based; and (3) to educate providers on the use of such materials. Patient decision aids developed under a grant or contract would be required to be designed to engage patients and present up-to-date clinical information that is age-appropriate and can be adapted for patients from a variety of cultural and educational backgrounds, among other requirements. The AHRQ Director would be required to provide for the dissemination of the patient decision aid materials to health providers and to the public, including via the Internet. The Director

would also be required to ensure that activities under the section are free from duplication of effort.

The Secretary would be required to award grants for establishing Shared Decision Making Resource Centers to educate providers, develop and disseminate best practices and other information to speed adoption and effective use of patient decisions aids and shared decision-making. The Secretary also would be required to award grants to providers for the development and implementation of shared decision-making techniques, making the awards in accordance with certain specifications. Finally, the Secretary would be required to adopt quality measures for shared decision-making, as specified. Providers receiving a grant would have to report to the Secretary data on those quality measures, and the Secretary would have to provide feedback to those providers. The reports would have to include an assessment of provider and patient satisfaction and experience with shared decision-making, among other items.

The proposal would authorize to be appropriated such sums as may be necessary for FY2010 and each subsequent fiscal year to carry out this section.

Sec. 218. Presentation of drug information.

Current Law

The introduction or delivery for introduction of a misbranded drug into interstate commerce is a prohibited act for which certain penalties may be imposed, according to the Federal Food Drug and Cosmetic Act (FFDCA; 21 USC 352), sections 301(a) and 303. A drug is deemed to be misbranded if it does not meet the requirements of FFDCA section 502. The section lists the items of information that must be listed in a drug's labeling (such as established name, quantity, active and inactive ingredients, adequate directions for use, and adequate warnings). The section also requires that each of these items be included prominently and conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In addition, the section requires that all advertisements and other descriptive printed matter include information in brief summary relating to side effects, contraindications, and effectiveness, as specified in regulation. See also: 21 CFR 201 (Labeling), and 21 CFR 202 (Prescription Drug Advertising).

Proposed Law

The bill would require the Secretary of Health and Human Services to determine whether the addition to a drug's labeling and print advertising of standardized, quantitative summaries of the benefits and risks of that drug in a tabular or drug facts box format (or any alternative format) would improve health care decision making by clinicians, and patients and consumers.

To reach that determination, the Secretary would act through the Commissioner of Food and Drugs to: review all available scientific evidence regarding the use of standardized,

quantitative summaries of the benefits and risks of drugs in a tabular or drug facts box or other format; and to consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, experts in geriatric and long-term care, and representatives of racial and ethnic minorities. The bill would require that the Secretary submit the determination and the reasoning and analysis underlying it in a report to Congress within one year of enactment.

If the Secretary determined that adding a differently formatted summary of information to a drug's labeling would improve health care decision making, the bill would require the Secretary to promulgate regulations within one year to implement that addition.

The Secretary would be required to ensure that information in the differently formatted summary is objective and up-to-date and is a result of a review process that considers the totality of published and unpublished data. The Secretary also would be required to post the differently formatted summary on the FDA Web site.

Sec. 219. Center for Health Outcomes Research and Evaluation.

Current Law

Title IX of the Public Health Service Act established both the Agency for Healthcare Research and Quality (AHRQ) and the National Advisory Council for Healthcare Research and Quality. AHRQ's statutory mission is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services. Its responsibilities include the conduct and support of research, the synthesis and dissemination of scientific evidence, and the advancement of efforts to improve health care quality. Among other topics, AHRQ activities address health disparities research, health care outcome improvement research, public-private partnerships, data collection regarding quality and cost of care, information systems, primary care and access in underserved areas, health care practice and technology innovation, and patient safety improvement.

In addition, section 902(c) provides the Director with the authority to provide financial assistance to assist in meeting the costs of planning and establishing new centers for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis.

Proposed Law

The bill would add a new section to the Public Health Service Act: Sec. 937. Center for Health Outcomes Research and Evaluation. The bill would require the Secretary to establish a Center for Health Outcomes Research and Evaluation (the Center) within AHRQ.

To identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically,

the bill would direct the Center to coordinate, conduct, support, and synthesize research relevant to the comparative health outcomes and effectiveness of the full spectrum of health care treatments, including pharmaceuticals, medical devices, medical and surgical procedures, screening and diagnostics, behavioral health care, and other health interventions. Responsibilities also would cover systematic reviews of clinical research, research that identifies scientific advances in personalized medicines, and research that reduces treatment disparities among populations.

The Center would be required to use a broad range of methodologies; create informational tools that organize, synthesize, and disseminate research findings to providers, patients, and public and private payers; and develop a publicly available resource database that collects and contains high-quality, independent evidence (from government and nongovernment sources) to inform healthcare decision-making. The bill would require the Center to submit to the Secretary and to Congress reports from grantees and contractors. The Center would also be required to encourage the development and use of clinical registries and the development of health outcomes research data networks from electronic health records, post marketing drug and medical device surveillance efforts, and other forms of electronic data.

The bill would require the Center to develop minimum methodological standards to be used when conducting studies of comparative health outcomes and value (and procedures for use of such standards) in order to help ensure accurate and effective comparisons and assessments of treatment options. Such standards would have to be developed within one year of enactment and to be updated at least biennially.

The bill would authorize the Center to secure directly from U.S. departments and agencies any information necessary to enable it to carry out this section. It would direct the heads of those departments and agencies to furnish the information to the Center on an agreed upon schedule.

The bill would direct the Center to use existing published and unpublished information "collected and assessed" by Center staff or under other arrangements; to carry out, or award grants or contracts for, original research and experimentation where existing information is inadequate; to adopt procedures for interested parties to submit information to the Center or the Advisory Counsel; and to comply with existing data privacy standards. The bill would require the Center to be subject to periodic audit by the Comptroller General.

To ensure transparency, the bill would require the Secretary to establish, through AHRQ's National Advisory Council, an advisory council that includes representatives from the scientific research, patient, provider, and health industry committees. Members shall include the Director and the Chief Medical Officers of the Centers for Medicare and Medicaid Services, and 19 other members representing a broad range of perspectives (epidemiology, health services research, bioethics, communication and decision sciences, health economics, and safe use of medical products) and specified health care communities (e.g., consumers, practicing physicians, nurses, employers, public payers,

insurance plans, and clinical researchers). The Secretary or the Secretary's designee would appoint members to staggered four-year terms and would take into consideration any financial conflicts of interest.

The bill would require actions to ensure transparency, credibility, and access to research conducted, supported, or synthesized under this section. To insulate the research agenda and research conduct from undo political or stakeholder influence, the bill would require that research use scientifically based methods, and take into account scientific advances in personalized medicine and research that reduces treatment disparities (that include ethnic and racial minorities and children). It would require all aspects of the research to be transparent to all stakeholders; public documentation and availability of the research process and methods; and establishment of a process for involved stakeholders to review and comment on the research. The bill would require consultation of representatives of specified groups regarding the priorities, conduct, and dissemination of the research, through transparent mechanisms to be recommended by the Council.

The Center would be required to post on its official Internet site appropriate information from each report (including interim, draft, and final reports, and stakeholder comments) submitted by a grantee or contractor. The bill also would require the Secretary to establish a process for the Center to share with Congress reports and nonproprietary data.

The bill would require the Center to disseminate to health care providers, patients, and other specified groups the findings of the research it supported, conducted, or synthesized. The bill specifies that Center reports and recommendations would not be permitted to be construed as mandates for payment, coverage, or treatment. The bill would require that the Center assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings into clinical practices; and establish a process to receive feedback about the value of information it disseminates.

The bill would require the Director of AHRQ to submit an annual report, beginning within one year of enactment, to Congress on the activities of the Center and the advisory council and the research conducted. The Secretary would be required to submit a report, not later than December 31, 2011, to Congress on all activities conducted or supported under this section, to include an evaluation of impact, overall costs, and an analysis of the backlog of approved but not funded research proposals. The Secretary's report would also address whether Congress should expand the Center's responsibilities to include studies of the effectiveness of various aspects of the health care delivery system.

Sec. 220. Demonstration Program to Integrate Quality Improvement and Patient Safety Training into Clinical Education of Health Professionals

Current Law

Under section 301 of the PHS Act, the Secretary has general authority to conduct and promote the coordination of research, investigations, experiments, demonstrations, and

studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases impacting individuals and to award grants for public health purposes, including for training; to award grants for training of health professionals under Part C of Title VII; and to conduct research and disseminate information regarding health care quality under Title IX; among other things.

Proposed Law

This proposal would allow the Secretary to award grants to eligible entities or consortia under this section to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals.

To be eligible to receive a grant under this provision, an entity or consortium would be required to 1) submit an application according to requirements of the Secretary; 2) be a health professions school; a school of public health; a school of social work; a school of nursing; a school of pharmacy; an institution with a graduate medical education program; or a school of health care administration; 3) collaborate in the development of curricula with an organization that accredits such school or institution; 4) provide for the collection of data regarding the effectiveness of the demonstration project; and 5) provide matching funds in accordance with this section.

A grant could be awarded under this section only if the receiving entity or consortium agrees to make available non-Federal contributions toward the costs of the program in an amount that is not less than $1 for each $5 of Federal funds. These non-Federal contributions may be cash or in kind, and may not include amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government.

This proposal would require the Secretary to evaluate the projects funded under this section and publish, make publicly available, and disseminate the results of such evaluations on as wide a basis as is practicable.

Finally, this proposal would require the Secretary to submit, to specified Congressional committees, a report that describes the specific projects supported under this section and contains recommendations for Congress based on the evaluation conducted per the requirements of this section.

Sec. 221. Office of Women's Health

Current Law

Among the Public Health Service (PHS) agencies, offices focused on women's health are established in law in the National Institutes of Health (NIH, in section 486(a) of the PHS Act) and the Substance Abuse and Mental Health Services Administration (SAMHSA, in section 501(f) of the PHS Act), and administratively in the Office of the Secretary (OS), and in the Centers for Disease Control and Prevention (CDC), Health Resources and

Services Administration (HRSA), and Food and Drug Administration (FDA). There is not currently an office for this purpose in the Agency for Healthcare Research and Quality (AHRQ).

Proposed Law

The proposal would establish, under a new PHS Act section 229, an Office of Women's Health (Office) in OS to be headed by a Deputy Assistant Secretary for Women's Health. The Secretary, acting through the Office, would be required to establish goals, establish a Coordinating Committee on Women's Health ("Coordinating Committee") composed of senior-level representatives from each HHS agency and office, and carry out additional activities as specified. The Secretary would be authorized to award grants to carry out this section, and would be required to: (1) conduct evaluations of funded projects, and (2) report to Congress regarding the activities of the office within one year of enactment, and every two years thereafter. The proposal would authorize for the purposes of this subsection the appropriation of such sums as may be necessary for FY2010–FY2014. The office would be required to assume all functions of the Office on Women's Health of the Public Health Service.

The proposal would also establish, under a new PHS Act section 310A, an Office of Women's Health in CDC, whose director would report to the CDC Director regarding CDC activities on women's health conditions (as defined), establish relevant goals and objectives, identify projects on women's health to be carried out by CDC, serve as a member of the Coordinating Committee, and carry out additional activities as specified. The proposal would authorize for the purposes of this subsection the appropriation of such sums as may be necessary for FY2010 through FY2014.

The proposal would amend current authority for offices of women's health in NIH and SAMHSA, to establish that the director of each respective office would report to the senior official of each respective agency.

The proposal would also establish, under a newly designated PHS Act section 927, an Office of Women's Health and Gender-Based Research in AHRQ, whose director shall report to the AHRQ Director regarding AHRQ activities on women's health, establish relevant goals and objectives, identify projects on women's health to be carried out by AHRQ, serve as a member of the Coordinating Committee, and carry out additional activities as specified. The proposal would authorize for the purposes of this subsection the appropriation of such sums as may be necessary for FY2010 through FY2014.

The proposal would also establish, under a new PHS Act section 713, an Office of Women's Health in HRSA, whose director would report to the HRSA Administrator regarding HRSA activities on women's health, establish relevant goals and objectives, identify projects on women's health to be carried out by HRSA, serve as a member of the Coordinating Committee, and carry out additional activities as specified. The director of the office would be required to continue implementation of existing women's health

activities at HRSA. The proposal would authorize for the purposes of this subsection the appropriation of such sums as may be necessary for FY2010 through FY2014.

The proposal would also establish, under a new section 911 of the Federal Food, Drug, and Cosmetic Act, an Office of Women's Health in FDA, whose director would report to the FDA Commissioner regarding FDA activities on women's health (including with respect to clinical trials), establish relevant goals and objectives, identify projects on women's health to be carried out by FDA, serve as a member of the Coordinating Committee, and carry out additional activities as specified. The proposal would authorize for the purposes of this subsection the appropriation of such sums as may be necessary for FY2010 through FY2014.

This section and amendments made by it would not alter existing regulatory authority, terminate (without the approval of Congress) authority away from women's' health offices in existence as of the date of enactment, or change existing administrative activities at HHS regarding women's health.

Sec. 222. Administrative Simplification

Current Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104-191) included a set of provisions, subtitled Administrative Simplification, requiring the HHS Secretary to develop standards to support the growth of electronic record keeping and claims processing in the health care system. The standards apply to health care providers (who transmit any health information in electronic form in connection with a HIPAA-specified transaction), heath plans, and health care clearinghouses. HIPAA instructed the Secretary to issue electronic format and data standards for nine routine administrative and financial transactions between health care providers and health plan/payers. Those transactions include claims and encounter information, payment and remittance advice, and claims status inquiry and response. The Secretary was to rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS), consult with appropriate Federal and State agencies and private organizations, and publish in the Federal Register any NCVHS recommendation regarding the adoption of a standard. HIPAA also instructed the Secretary to review and, not more frequently than once a year, modify the Administrative Simplification standards. Again, the Secretary was to rely on the recommendations of the NCVHS and publish in the Federal Register any NCVHS recommendation regarding the modification of a standard. Any such modification has to be completed in a manner that minimizes disruption and the cost of compliance.

HIPAA does not mandate that providers submit transactions electronically, though health plans/payers increasingly require it. However, if a health care provider chooses to submit one or more of the HIPAA-specified transactions electronically, then he or she must comply with the standard for that transaction. In 2001, Congress enacted the

Administrative Simplification Compliance (P.L. 107-105), which, among other things, requires Medicare providers to submit claims electronically.

HIPAA further required the Secretary to issue national identification numbers for health care providers, health plans, employers, and individuals (i.e., patients) for use in standard transactions. Unique identifiers for providers and employers have been adopted, while the health plan identifier is still under review.

Proposed Law

The proposal would require the Secretary, within two years of enactment of this Act and building on existing standards and related requirements, to adopt and regularly update a set of standards, implementation specifications, and operating rules for electronic financial and administrative transactions. The standards, implementation specifications, and operating rules would be required to: (1) be unique with no conflicting or redundant standards; (2) be authoritative, requiring no additional standards; (3) be comprehensive and robust, requiring minimal augmentation by paper transactions; (4) enable real-time determination of a patient's financial responsibility at the point of service; (5) provide for timely acknowledgment; and (6) require that all data elements within a standard, specification, or criteria be described in unambiguous terms with no optional fields permitted. Further, the initial set of standards, implementation specifications, and operating rules must include requirements to clarify, refine, and expand the HIPAA Administrative Simplification standards. In addition, they must include requirements for acknowledgments (such as those for receipt of a claim) and to permit electronic funds transfers, as well as requirements for timely and transparent claim and denial management processes and other functions relating to administrative simplification as identified by the Secretary. Within two years of enactment of this Act, the Secretary would be required to submit to Congress a five-year implementation and enforcement plan for the new standards, implementation specifications, and operating rules.

Within one year of enactment of this Act, the Secretary would be required to promulgate a final rule to establish a National Health Plan Identifier system.