



Continua
HEALTH ALLIANCE

March 2, 2011

Internal Revenue Service
111 Constitution Ave., NW
Washington DC 20224
Attn: CC:PA:LPD:PR
(Notice 2010-89)

Electronically delivered via Notice.Comments@irs.counsel.treas.gov

Re: Notice 2010-89

On behalf of the Continua Health Alliance I am pleased to provide comments concerning the medical device excise tax (the “device tax”) enacted as new Internal Revenue Code (the “Code”) section 4191 under section 1405 of the Health Care and Education Reconciliation Act of 2010 (HCERA), which amended the Patient Protection and Affordable Care Act (PPACA) collectively, the Affordable Care Act or “ACA”. We appreciate the efforts being made by the IRS and Treasury to obtain information from the industry in advance of developing guidance on the device tax. In developing final rules, clarity with respect to the application of the tax in various contexts will be essential for the affected industries to properly implement the tax.

Continua is a non-profit, open industry coalition of nearly 240 members representing healthcare, technology and medical device companies joining together in collaboration to improve the quality of health through the use of telehealth, personal connected health, mobile health (mHealth) and independent living technologies for what has been termed “e-Care” by the Federal Communications Commission.¹ Continua is dedicated to establishing interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals, and provides the opportunity for personalized health and wellness. More information about Continua and its members can be found at www.continuaalliance.org.

Defining “e-Care”

The term “e-Care” as defined by the FCC in its National Broadband Plan, is “the electronic exchange of information – data, images and video – to aid in the practice of

¹ FCC National Broadband Plan: Connecting America, released March 16, 2010, at Page 200. See U.S. Senate Special Committee on Aging, Committee Hearing on April 22, 2010 “Aging in Place: The National Broadband Plan and Bringing Health Care Technology Home” http://aging.senate.gov/hearing_detail.cfm?id=324102&.

medicine and advanced analytics. [It] encompasses technology that enables video consult, remote patient monitoring and image transmission (“store and forward”) over fixed or mobile networks.” Thus, an example of an e-Care device is a device that measures the oxygen in an individual’s blood and sends the information directly and electronically to the individual’s personal or electronic health record.

Continua believes that remote patient monitoring (RPM) devices qualify for the exception to the device tax for devices generally sold to the general public at retail. Remote patient monitoring devices are:

- ***For individual use.*** These devices are specifically intended for use in the home. They are not used in provider offices or in hospitals.
- ***Generally sold to the general public at retail.*** There is a broad range of devices that fall into the category of e-Care. Some devices are leased to individuals for their personal use in their homes, while others are sold at electronic stores, drug stores or on-line. As this emerging technology continues to evolve, the market trend is for more sales in stores and on-line.

BACKGROUND

Remote Patient Monitoring Devices

e-Care technologies encompass a newly evolving sector, that relies on wired, wireless and mobile broadband and Internet services to support healthcare through devices that remotely assist and monitor patients. These health information technologies are designed to assist people with heart disease, diabetes or other chronic diseases by transmitting vital diagnostic and biometric indicators such as blood pressure, heart rate, oxygen saturation, glucose levels, temperature, weight, respiration - seamlessly from readily available medical devices within a patient’s home to his health professional, care coordinator or loved one. Whether by recording and storing data, or in a real-time format, the idea is to provide information on a patient in a consistent and reliable manner. That information can be used to track, make treatment decisions, and help diagnose patients as needed. These technologies are not intended to replace the work of healthcare professionals or providers.

Today, technologies like these can enable a more proactive approach to personal health, and also keep with the vision of the Affordable Care Act to create a coordinated health care system that improves quality of life, and eliminates unnecessary costs like avoidable hospital readmissions. Continua’s vision is for its members to develop interoperable

personal health solutions that empower people and organizations to better manage health, wellness and fitness. Interoperable health devices:

- Empower individuals and patients to better manage their health by providing them with information regarding their health through personal health and medical devices and services.
- Allow loved ones and professional care givers to more accurately monitor and coach chronic disease patients and elderly individuals living independently.
- Enable health care providers to offer better quality care through personalized health solutions commercially available from a rich marketplace of interoperable health, wellness and medical devices and services.

While many remote devices are produced by brands well known in the technology industry, many are also created by start-up companies.

Reimbursement and Insurance Coverage

To date private coverage as well as Medicare/Medicaid coverage is negligible. Therefore, the patient more often is paying for the cost of the device or leasing the device with his own out of pocket dollars.

DISCUSSION AND ANALYSIS

I. Statutory Provisions

Code Section 4191 imposes a tax on the sale of any “taxable medical device” by the manufacturer, producer or importer of the device. The term “taxable medical device” is defined generally in Section 4191(b)(1) to mean any device as defined in section 204(h) of the Federal Food, Drug, & Cosmetic (FD&C) Act that is intended for humans. The term “taxable medical device” does not include eyeglasses, contact lenses, hearing aids, or “any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.” Code §4191(b)(2). The last exception is referred to here as the “retail sale exception.”

Devices may qualify for the retail sale exception even if some sales are not at retail or not to the general public. Devices of any classification (i.e., Class I, Class II or Class III) may be exempted under this exception.

Section 4191 does not contain a definition of what is considered a sale “at retail” for purposes of the device tax. Preexisting excise tax provisions in the Code define a retail sale as a sale for a purpose other than resale, after manufacture, production, or importation. See Code §4002(a). The Technical Explanation of ACA produced by the

Joint Committee on Taxation describes the exception as including devices “generally sold at retail establishments (including over the internet) to individuals for their personal use.”²

We believe that remote patient monitoring devices qualify for the retail sale exception.

II. Remote Patient Devices Are Generally Purchased by the General Public at Retail for Individual Use and Therefore Should Not be Subject to the Device Tax

Remote Patient Devices Meet the Statutory Requirements for Exemption from the Tax

We believe that remote patient devices satisfy the requirements for the retail sale exception. There should be little doubt that the devices are for individual use. In fact, the purpose of this developing technology is to allow individuals to care for themselves (or their loved ones) in their own homes or for individual use outside the home. These are not the same devices used in hospitals to monitor patients.

Remote monitoring devices are generally purchased by the general public at retail, even when they require a doctor’s prescription, much like contacts or hearing aids. Many of the devices are available from electronic stores, drug stores and on-line. In other cases, due primarily to the fact that the devices are an emerging technology and are of higher cost, the devices are purchased by health care providers and then leased to the individual for use by that individual in their residence.

The retail sale exception does not require that all sales of a device be to the general public, nor does it look to each sale in particular, but rather to the general method of sale of the product. As indicated, in the House version of ACA, the device tax was aimed at devices sold “for use in connection with providing any health care service”. That is, the device tax is focused on devices generally sold to hospitals, doctors, and other health care providers for use in providing medical services, rather than devices that are generally delivered directly to individuals for their personal use.

Thus, the fact that some sales to individuals are currently facilitated through a leasing intermediary should not disqualify the device from the exception. Further, the market trend is for purchases in pharmacies (or similar retail outlets) and on-line to increase, and we expect this to continue over time.

The Affordable Care Act Indicates Congressional Intent to Exempt Remote Devices from the Device Tax

² Joint Committee on Taxation, *Technical Explanation of the Revenue Provisions of the “Reconciliation Act of 2010,” as Amended, in Combination with the “Patient Protection and Affordable Care Act”* (JCX-18-2010) March 21, 2010, at 138.

The Affordable Care Act contains many provisions that are designed to promote and encourage the use of new technologies in general, and remote monitoring devices in particular.

The Affordable Care Act encourages the use of remote patient monitoring using a variety of descriptive phrases to capture what remote patient monitoring can do. For example, Section 3022 of the Accountable Care Organizations requires patient engagement through telehealth, remote patient monitoring and other similar forms of enabling technology. The Independence at Home Demonstration Project (section 3024) creates a new demonstration program for chronically ill Medicare beneficiaries and defines an “independence at home medical practice” as one that “uses electronic health information systems, remote monitoring and mobile diagnostic technology.”

It would be counter-intuitive that Congress would encourage the development of a coordinated care system using remote monitoring and then retard its development through a tax.

The chart in the Appendix lists provisions in ACA and HCERA. This chart captures many, but not all of the provisions that are most relevant. While we believe the statutory requirements for the exception are met, to apply the tax in this context would also clearly undermine the strong commitment in ACA to promote remote monitoring.

III. Implementation of the Device Tax Must Accommodate Emerging Technologies

As the definition of e-Care adopted by the FCC indicates, remote monitoring devices encompass a broad spectrum of technologies. Advances in technology should be taken into account while contemplating the implementation of the device tax. The devices described herein are intended to be sold at retail, including any software applications or “apps” having been cleared or approved for sale by the Food and Drug Administration (FDA) as medical devices. Any remote monitoring device that meets this definition and sold at retail should qualify for the retail sale exception (if it is considered a “device” by the FDA).

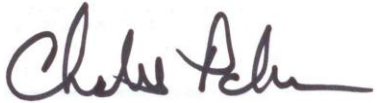
In addition, because technology is evolving, the initial cost for some devices is high. For this reason, some devices are leased on a monthly basis from a provider. Should the final guidance rely on a de minimus amount for an exemption, Continua would urge the agency to ensure that such an amount is a per month amount and reflects the fact that technology is evolving and often comes to market at an initial cost that reduces over time. Because of the lack of health insurance coverage, lease arrangements may be more practical, initially.

CONCLUSION

In conclusion, Continua urges you to exempt remote patient monitoring devices used at home (whether purchased or leased) by an individual for personal use from the medical device tax.

If we can provide any further information as this process is developed, please do not hesitate to contact Chuck Parker, Executive Director, Continua Health Alliance (chuck.parker@continuaalliance.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Charles Parker". The signature is fluid and cursive, with the first name "Charles" being more prominent than the last name "Parker".

Charles Parker
Executive Director
chuck.parker@continuaalliance.org
503.619.0867

Appendix

Telehealth/HIT Provisions	H.R. 3590 and H.R. 4782
Administrative/Enrollment Simplification	<p>Accelerates HHS adoption of uniform standards and operating rules for the electronic transactions that occur between providers and health plans that are governed under HIPAA, including benefit eligibility verification, prior authorization, and electronic funds transfer payments. Requires that standards: enable determination of eligibility; be comprehensive; provide for a transparent claims and denial management process, and; describe all data elements in unambiguous terms. Establishes a process, using recommendations of a qualified nonprofit entity and the National Committee on Vital and Health Statistics, to regularly update the standards and operating rules for electronic transactions. Requires health plans to certify compliance or pay a penalty fee. Provides for an additional penalty for misrepresentation of compliance. Includes deadlines for various rulemaking, including: unique health plan identifier; electronic funds transfer, and; health claims attachments. <i>(Sec. 1104)</i></p> <p>Requires, within 180 days after enactment, the Secretary to develop standards and protocols, in consultation with the HIT Policy and Standards Committees, to promote the interoperability of systems for enrollment of individuals in Federal and State health and human services programs. These standards shall allow for electronic matching against federal and state data, simplification of electronic documentation, reuse of stored eligibility information, capability for individuals to apply, recertify and manage their information online, ability to expand enrollment system to integrate new programs, rules and functionalities, notification of eligibility, recertification and other communication, and other functionality to streamline the enrollment process. The Secretary may require State or other entities to incorporate such standards as a condition of receiving Federal health information technology funds. Provides grants for state and local government entities to develop new and adapt existing technology systems to implement the HIT enrollment standards and protocols developed under this section. <i>(Sec. 1561)</i></p> <p>Requires the Secretary of HHS to develop a plan (and a detailed budget for the resources needed to implement such plan) to modernize the computer and data systems of CMS to support improvements in care delivery. <i>(Sec. 10330)</i></p>
Rewarding Quality through Market Based Incentives	<p>Requires the Secretary, in consultation with stakeholders, to develop guidelines for a payment structure that provides increased reimbursement or other incentives for improving health outcomes through quality reports, case management, care coordination, chronic disease management, medication and care compliance initiatives (including medical home); activities to reduce hospital readmissions; activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology; and wellness and health promotion activities. <i>(Sec. 1311)</i></p>
Accountable Care Organizations	<p>Not later than January 1, 2012, requires the Secretary to establish a shared savings program that would reward Accountable Care Organizations (“ACOs”) that take responsibility for the costs and quality of care received by their patient panel over time. ACOs can include groups of health care providers (including physician groups, hospitals, nurse practitioners and physician assistants, and others). ACOs that meet quality-of-care targets and reduce the costs of their patients relative to a spending benchmark are rewarded with a share of the savings they achieve for the Medicare program (as determined by the Secretary). Requires ACOs to “define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote</p>

	patient monitoring, and other such enabling technologies.” (Sec. 3022)
Physician Face-to-Face Encounter Requirement	Requires physicians to have a face-to-face encounter (or through the use of telehealth and other than with respect to encounters that are incident to services involved) with patients within a reasonable timeframe as determined by the Secretary under Part A or within six months or a reasonable time as determined by the Secretary under Part B prior to certification or re-certification for home health services under Medicare. Payment for durable medical equipment is subject to this requirement and the face-to-face encounter must occur within six months of the written order. Allows the Secretary to extend the requirement of a face-to-face (or telehealth) encounter to other items or services, if the Secretary determines it would reduce the risk of fraud and abuse. Applies the face-to-face encounter requirements for home health services, durable medical equipment, and any other applicable item or service identified by the Secretary to items or services paid for under Medicaid. (Sec. 6407)
Annual Wellness Visit	Provides coverage under Medicare for an annual wellness visit where individuals are provided personalized prevention plan services. These services would include the creation of a plan that includes a health risk assessment, takes into account the results of the assessment, and may contain various elements including a screening schedule for the next 5 to 10 years. Provides that a health risk assessment “may be furnished through an interactive telephonic or web-based program” that meets standards established by the Secretary no later than one year after enactment of the bill. No co-payment or deductible would apply. Effective on or after January 1, 2011. (Sec. 4103)
Independence At Home Demonstration Project	Creates a new demonstration program to begin not later than January 1, 2012, for chronically ill Medicare beneficiaries to test a payment incentive and service delivery system that utilizes physician and nurse practitioner directed home-based primary care teams aimed at reducing expenditures and improving health outcomes. Defines an “independence at home medical practice” as one that “uses electronic health information systems, remote monitoring, and mobile diagnostic technology.” Provides preference for independence at home medical practices that are located in high-cost areas of the country, have experience in furnishing health care services to applicable beneficiaries in the home, and use electronic medical records, health information technology, and individualized plans of care. Appropriates \$5 million for each of fiscal years 2010 through 2015. (Sec. 3024)
Center for Medicare and Medicaid Innovation	Establishes within the Centers for Medicare and Medicaid Services (CMS) a Center for Medicare & Medicaid Innovation. The purpose of the Center will be to research, develop, test, and expand innovative payment and delivery arrangements (models) to improve the quality and reduce the cost of care provided to patients in each program. For purposes of testing payment and service delivery models, the Secretary may limit testing of a model to a certain geographic area. Successful models can be expanded nationally. (Successful models are those that improve patient care without increasing spending. Specifies that the Secretary should focus on models that improve the quality of patient care and reduce spending.) Specifies a number of models to be tested but does not limit testing to these models. The bill describes certain models, which could be tested, including models that: (i) support “care coordination for chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home telehealth technology;” (ii) “facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems;” and (iii) utilize particularly “in entities located in medically underserved areas and facilities of the Indian Health Service . . . telehealth services in treating behavioral health issues (such as post-traumatic stress disorder) and stroke and to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex

	<p>conditions.” Also provides additional factors for consideration, including “whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.” The Center would be required to conduct an evaluation of each model tested, including an analysis of (i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and (ii) the changes in spending by reason of the model. The scope of the Innovation Center may include the Medicaid and CHIP programs, with the same requirements for testing and evaluation of patient-centered delivery and payment models that have shown evidence of success in Medicaid and CHIP populations as proposed for Medicare. The Center is exempted from budget-neutrality requirements for an initial testing period. Appropriates \$5 million from the Treasury not otherwise appropriated for the design, implementation, and evaluation of models for FY 2010; and appropriates \$10 billion for Center activities over 10 years. <i>(Sec. 3021)</i></p>
<p>Community Health Teams to Support the Medical Home</p>	<p>Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities that can establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital services areas served by the entities. Also requires the health teams to “support patient-centered medical homes” defined as a “mode of care that includes. . .safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements.” Participating entities shall submit to the Secretary a report that describes and evaluates the activities carried out by the entity. <i>(Sec. 3502)</i></p>
<p>Primary Care Training and Enhancement</p>	<p>Provides grants and contracts to support and develop primary care training programs through accredited public or nonprofit hospitals, schools of medicine, physician assistant training programs or other public or nonprofit entities the Secretary determines are capable of carrying out a grant or contract. Provides grants or contracts for capacity building in primary care through accredited schools of medicine. Grants or contracts will be used to develop and operate training programs, provide financial assistance to trainees and faculty, enhance faculty development in primary care and physician assistant programs, and establish, maintain, and improve academic units in primary care. Priority is given to programs for a number of reasons, including to those that educate students in team-based approaches to care, including the patient-centered medical home and those approaches that “provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology or other competencies recommended by the Advisory committee on Training in Primary Care Medicine and Dentistry and the National Health Care workforce Commission.” Awards would be for a period of 5 years. Authorizes \$125 million for 2010 and such sums as may be necessary for 2011-2014. <i>(Sec. 5301)</i></p>
<p>Medicare Advantage</p>	<p>H.R. 4782 REPEALED Sec. 3201 of H.R. 3950 that would have created a care coordination and management performance bonus for MA plans that implement programs, such as “health information technology programs, including clinical decision support and other tools to facilitate data collection and ensure patient-centered, appropriate care.”</p> <p>H.R. 4782 adds:</p> <p>Beginning in 2012, provides quality-based bonus payments to plans receiving 4 or more stars on a 5-star scale based on data currently collected. Provides for a 1.5 percent bonus in 2012; a 3 percent bonus in 2013; and a 5 percent bonus in 2014 and subsequent years. Provides for double bonuses for qualifying plans in qualifying counties. For plan years 2012-2014, phases in a modified beneficiary rebate system based on quality scores. As of 2014, plans with a quality rating of at least 4.5 stars can offer rebates (as offered now, in</p>

	<p>the form of additional benefits, reduced cost sharing, etc.) of 70 percent of the difference between the benchmark and the bid; for plans with 3.5-4.5 stars, 65 percent; and for plans with less than 3.5 stars, 50 percent. <i>(Sec. 1102)</i></p>
<p>Skilled Nursing Facilities/Long-Term Care Facilities</p>	<p>Authorizes the Secretary to make grants to long-term care facilities for the purpose of assisting such entities in off-setting the costs related to purchasing, leasing, developing, and implementing certified EHR technology. The Secretary shall adopt electronic standards for the exchange of clinical data by long-term care facilities. No later than 10 years after enactment of the Act, the Secretary shall have procedures in place to accept the optional electronic submission of clinical data by long-term care facilities. For this program, along with other grant programs for the enhancement of long-term care, appropriates \$20 million for FY 2011, \$17.5 million for FY 2012, and \$15 million for each of FYs 2013 and 2014. <i>(Sec. 6703 adding Sec. 2041)</i></p> <p>Requires the Secretary to conduct two facility-based demonstration projects that would develop best practice models in two areas. The first would be designed to identify best practices in facilities that are involved in the “culture change” movement, including the development of resources where facilities may be able to access information in order to implement culture change. The second demonstration would focus on development of best practices in information technology that facilities are using to improve resident care. <i>(Sec. 6114)</i></p>
<p>Workforce Advisory Committee</p>	<p>Establishes a national commission tasked with reviewing health care workforce and projected workforce needs. The overall goal of the Commission is to provide comprehensive, unbiased information to Congress and the Administration about how to align Federal health care workforce resources with national needs. Congress will use this information when providing appropriations to discretionary programs or in restructuring other Federal funding sources. Highlights high priority areas for consideration by the commission, including “an analysis of the nature, scopes of practice, and demands for health care workers in the enhanced information technology and management workplace.” The commission shall be composed of 15 members appointed by the GAO, including at least one representative of the following: health care workforce and health professionals, employers, third-party payers, individuals skilled in health care-related research, consumers, labor unions, state/local workforce investment boards, and educational institutions. <i>(Sec. 5101)</i></p>
<p>State Option to Provide Health Homes for Individuals with Chronic Conditions in Medicaid</p>	<p>Creates a new Medicaid state plan option under which enrollees with at least two chronic conditions, or with one chronic condition and at risk of developing another, or with at least one serious and persistent mental health condition, could designate a provider, a team of health care professionals, or a health team as their health home. Qualifying providers would have to meet certain standards established by the Secretary, including demonstrating that they have systems and infrastructure in place to provide comprehensive and timely high-quality care either in-house or by contracting with a team of health professionals. The designated provider or team would offer comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support; referral to community and social support services, if relevant; and as feasible use health information technology to link such services. Teams of providers could be a freestanding, virtual, or hospital-based, community health center, community mental health center, clinic, physician’s office, or physician group practice. Designated providers would be required to report to the state on all applicable quality measures in the state Medicaid program.</p> <p>The state would develop a mechanism to pay the health home, and the state plan amendment would include a plan for tracking avoidable hospital readmissions and for calculating savings resulting from improved chronic care coordination and management. States will also include in their state plan amendments “a proposal for use of health information technology in providing health home services under this</p>

	<p>section and improving service delivery and coordination across the care continuum (including the use of wireless patient technology to improve coordination and management of care and patient adherence to recommendations made by their provider).” Requires providers to report on applicable measures and to use health information technology to report these measures, where feasible and appropriate. When appropriate the state will consult and coordinate with the Substance Abuse and Mental Health Services Administration specifically in addressing the prevention and treatment of mental illness and substance abuse.</p> <p>Provides an enhanced match of 90% FMAP for 2 years for states that take the option. Small planning grants may be available to help states intending to take the option. FMAP rules would apply.</p> <p>Requires the Secretary to survey states and report to Congress on the nature, extent, and use of this option, particularly as it pertains to hospital admission rates, chronic disease management, and coordination of care for the chronically ill. The state option would be available beginning on January 1, 2011. An independent evaluation of the impact of this option on reducing hospital admissions, emergency room visits, and admissions to skilled nursing facilities would be conducted. <i>(Sec. 2703)</i></p>
Comparative Effectiveness Research	<p>Establishes a private, non-profit corporation to assist providers, payers, and policy makers in making informed health decisions. Research conducted would be comparative clinical effectiveness research, which is research that evaluates and compares the health outcomes and clinical effectiveness, risks, and benefits of two or more medical treatments, services, or items. Defines treatment, services, and items as: health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologics), integrative health practices, and any strategies or items used in the treatment, management, diagnosis, or prevention of illness or injury in patients. Requires dissemination of the research information to health care providers, patients, vendors of health information technology focused on clinical decision support, relevant expert organizations, Federal and private health plans, and other relevant stakeholders. <i>(Sec. 6301)</i></p>
Assistant Secretary for Health Information/Key Health Indicators	<p>Establishes a Commission on Key National Indicators to conduct a comprehensive oversight of a newly established key national indicators system, with a required annual report to Congress. <i>(Sec. 5605)</i></p>
Community-Based Collaborative Care Networks	<p>Provides grants to eligible entities to support community-based collaborative care networks, defined as a consortium of providers with a joint governance structure that provides comprehensive coordinated and integrated care to low-income populations. Networks must include (1) a hospital meeting the required level of Medicaid inpatient utilization or low-income utilization that applies to disproportionate share hospitals, and (2) all FQHCs located in the community. Grant funds could be used to assist low-income individuals to access and appropriately use health services, enroll in health coverage programs and obtain a regular primary care provider or medical home; provide case management and care management; perform health outreach using neighborhood health workers or other means; provide transportation; expand capacity through telehealth, after-hours services or urgent care; and provide direct patient care services. Authorizes such funds as may be necessary for 2011-2015. <i>(Sec. 10333)</i></p>
Indian Health	<p>With amendment, incorporates S. 1790 entitled “A bill to amend the Indian Health Care Improvement Act to revise and extend that Act, and for other purposes.” Senate section-by-section states that the bill includes “programs to increase the Indian health workforce, establish new programs for innovative care delivery models, behavioral health services, new services for health promotion and disease prevention, efforts to improve access to health care services, construction of Indian health facilities, and an Indian youth suicide prevention grant program.” <i>(Sec.</i></p>

	<i>10221)</i>
Physician Quality Reporting Initiative	Extends the PQRI program through 2014. For 2011, incentive payments would equal 1.0 percent and 0.5 percent for 2012, 2013, and 2014. Eligible professionals who do not report quality data measures would be penalized by 1.5 percent for 2015 and 2 percent for 2016. The Secretary shall provide timely feedback to eligible professionals on their performance with respect to satisfactorily submitting data on quality measures. Not later than January 1, 2011, requires the Secretary to implement an informal process under which an eligible professional may appeal a payment decision made under the program. Not later than January 1, 2012, the Secretary shall develop a plan to integrate the clinical reporting on quality measures with the reporting requirements relating to the meaningful use of electronic health records (EHRs). For years after 2010, eligible professionals would be permitted to participate in the PQRI program through Maintenance of Certification programs operated by a specialty body of the American Board of Medical Specialties that meet the registry requirements. <i>(Sec. 3002)</i>
Part D Medication Therapy Management Programs	Beginning with plan years that begin on or after 2 years after enactment, Part D prescription drug plan sponsors would be required to offer MTM services to targeted beneficiaries, including an annual comprehensive review of medications (either in person or through telehealth technologies as defined by the Secretary) by a licensed pharmacist or other qualified provider, which may result in an action plan; a written summary of the review in a standardized format; and follow-up interventions as warranted based on the findings of the review (which may be provided person-to-person or using telehealth technologies as defined by the Secretary). Sponsors would be required to assess on at least a quarterly basis the medication use of individuals who are at risk but not enrolled in the MTM program. Plans must also enroll beneficiaries who qualify on a quarterly basis and allow for opt out. <i>(Sec. 10328)</i>
Incentives for State Medicaid Programs to Offer Home and Community-Based Services	Adds a new policy that creates financial incentives for States to shift Medicaid beneficiaries out of nursing homes and into home and community based services (“HCBS”). The provision provides Federal Medical Assistance Percentage (“FMAP”) increases to States to rebalance their spending between nursing homes and HCBS. <i>(Sec. 10202).</i>
Quality and Efficiency Measures	Provides \$20 million to support the endorsement and use of endorsed measures by the HHS Secretary for use in Medicare, reporting performance information to the public, and in health care programs. Specifically, the Secretary would establish a pre-rulemaking process to obtain input from the consensus-based entity and multi-stakeholder group on the selection of quality and efficiency measures. By not later than December 1 each year, starting in 2011, the Secretary shall make public a list of measures being considered for selection with respect to Medicare reporting and payment systems. The Secretary may include measures that have and have not been endorsed by the consensus-based entity. Not later than February 1, the consensus-based entity must give the Secretary its recommendations regarding the proposed measures. The entity would convene the stakeholder group to consult on the recommendations. The entity would ensure an open and transparent process. <i>(Sec. 3014) (Manager’s amendment clarifies that efficiency measures should also be included. Quality measure provisions were in original bill.)</i>