Congressional Research Service

**MEMORANDUM** February 24, 2012

**To:** Sen. Tom Coburn
Attention: Josh Trent

**From:** Jim Hahn, Specialist in Health Care Financing, 7-4914

**Subject:** **Center for Medicare and Medicaid Innovation**

This memo addresses certain of your questions about the Center for Medicare and Medicaid Innovation (CMMI).[1]

**1. Please describe the CMMI authorities outlined in law as specifically as possible.**

The Social Security Amendments of 1967, as amended by the Social Security Amendments of 1972, provide the Secretary with broad authority to develop and engage in experiments and demonstrations to test new approaches to paying providers, delivering health care services, or providing benefits to beneficiaries participating in federal health care programs. All demonstrations are required to be budget neutral and be approved by the Office of Management and Budget (OMB) prior to implementation.

***Scope.*** Section 3021 of the ACA establishes a new §1115A within the Social Security Act (SSA) which requires the Secretary to establish the CMMI within the Centers for Medicare & Medicaid Services (CMS).[2] The purpose of the CMMI is to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care for program beneficiaries. In selecting these models, the Secretary is required to give preference to models that improve the coordination, quality, and efficiency of health care services. In carrying out its functions, the Secretary is required to consult with relevant federal agencies and experts in medicine and health care management. The purpose of the center will be to research, develop, test, and expand innovative payment and delivery arrangements to improve the quality and reduce the cost of care provided to patients. Successful models could be expanded nationally.

***Testing (Phase I).*** The Secretary is required to select models that address a defined population with poor clinical outcomes or avoidable expenditures. The Secretary has the authority to limit

[1] Responses to additional questions are being prepared by the American Law Division.

[2] ACA establishes the Center for Medicare and Medicaid Innovation as CMI; however, CMS uses the acronym "CMMI" for the Center.

testing to certain geographic areas and select demonstration models that address a variety of themes, including medical homes, coordinated care, alternative payment mechanisms, health information technology (HIT), medication management, patient education, integrated care for dual-eligibles, care for cancer patients, post-acute care, chronic care management, telehealth, and collaboration among mixed provider types. The Secretary will not have to require, as a condition for testing, that the model be budget neutral initially with respect to expenditures. When selecting models, the Secretary is authorized to consider additional factors such as whether the model includes a process for managing patient care plans, places the applicable individual at the center of the care team, utilizes technology, and demonstrates effective linkage with other private and public sector payers, among other elements.

***Evaluation.*** The Secretary is required to conduct an evaluation of each model tested and make the evaluations publicly available in a timely fashion. Evaluations are required to include an analysis of (1) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria as determined by the Secretary, and (2) the changes in spending. The Secretary may require States and other entities participating in the demonstrations to collect and report information necessary to evaluate these models.

***Termination Authority.*** The Secretary has the authority to and must terminate or modify demonstrations that do not meet one of three conditions: (1) improve quality without increasing spending; (2) reduce spending without reducing quality; or (3) improve quality and reduce spending.

***Expansion Authority (Phase II).*** Taking into account the results of an evaluation, the Secretary has the authority to expand the duration and scope of a demonstration, including nationwide, if the Secretary determines that an expansion would: (1) reduce spending without reducing quality or improve quality without increasing spending; (2) reduce (or not increase) net program spending under applicable titles as certified by the CMS Office of the Actuary (OACT); and (3) not deny or limit coverage.

***Waiver Authority.*** The Secretary has the authority to waive requirements of Titles XI, Titles XVIII, and sections 1902(a)(1), 1902(a)(13), and 1902(m)(2)(A)(iii) of the SSA as necessary to conduct these demonstrations. The enabling statute also exempts the testing, evaluation, and expansion of demonstrations from Chapter 35 of title 44, the Paperwork Reduction Act (PRA), which requires federal agencies to receive OMB approval for each collection of information request.

***Oversight.*** Beginning in 2012, the Secretary is required to submit a report to Congress on the activities performed by the CMMI, at least once every other year. The reports must include a description of the demonstrations, the number of participants, the amount of payments made on behalf of these participants, models chosen for expansion, and evaluation results. Reports are also required to include recommendations for legislative action to facilitate the development and expansion of such models nationwide.

**2. Are there any required specifics to what types of models must be explored, other than: (a) [the] qualitative requirement that the model shall improve care as determined by [the] CMS Administrator (Are there any external reviews or checks on the CMS administrator's definition of "improving care"?), or (b) [the] quantitative requirement that the model reduce spending?**

The statute requires that the Secretary select from those "models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[3] The statutory provisions then list numerous "opportunities" and describe a number of models that the Secretary ***may*** select, including medical homes, coordinated care, community-based health teams, and others,[4] as well as "additional factors" that the CMMI ***may*** consider, but there is no mandate that any of these be among the selected models.

There are no references in statute to any external reviews or checks on the CMS administrator's definition of "improving care." In fact, the CMMI implementation statute sets limitations such that there will be no administrative or judicial review of "(A) the selection of models for testing or expansion under this section, (B) the selection of organizations, sites, or participants to test those models selected, (C) the elements, parameters, scope, and duration of such models for testing or dissemination, (D) determinations regarding budget neutrality, (E) the termination or modification of the design and implementation of a model, and (F) determinations about expansion of the duration and scope of a model, including the determination that a model is not expected to meet criteria."[5]

The CMMI is required to "consult representatives of relevant Federal agencies and clinical and analytic experts with expertise in medicine and health care management" in carrying out its duties and to "use open door forums or other mechanisms to seek input from interested parties".

**5. The statute seems silent on the duration of Phase I and Phase II. Could it be permissible under the law for the Secretary to run a Phase I pilot for an extended period of time — say, several years?**

The statue does not mention any specific time frames. However, under Phase I, the Secretary must "terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the CMS, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to (i) improve the quality of care (as determined by the CMS Administrator) without increasing spending under the applicable title, (ii) reduce spending under the applicable title without reducing the quality of

[3] Social Security Act Sec. 1115A(b)(2).

[4] Social Security Act Sec. 1115A(b)(2)(B).

[5] Social Security Act Sec. 1115A(d)(2).

care, or (iii) improve the quality of care and reduce spending."[6] Termination could occur at any time after the beginning and before completion of the testing.

**6. Is there anything in the statute that would prohibit the Secretary from implementing multiple pilots —say, a dozen or so — nationwide with a short time frame —say, within months or a soon as rulemaking could be completed?**

Nothing in statute would appear to expressly prohibit this scenario. However, there are requirements associated with each pilot that might create practical impediments to doing so. For example, the Secretary must conduct an evaluation of each model tested, and each evaluation must include 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 under the applicable titles by reason of the model."[7] The results of each evaluation must be made "available to the public in a timely fashion" and the Secretary "may establish requirements for States and other entities participating in the testing of models under this section to collect and report information that the Secretary determines is necessary to monitor and evaluate such models."[8]

**9. Are there any requirements that CMMI consider past pilots CMS has implemented in order to learn from ineffective pilots? Are there any requirements that prevent duplication of other existing efforts within CMS?**

There are no provisions in the enabling statute that require CMMI to consider past CMS pilots in its deliberations, However, it does appear that CMMI is building on past demonstration projects, as indicated in its Bundled Payment for Care Improvement Initiative (Bundled Payment Initiative). In that request for application (RFA), CMMI discusses three prior Medicare demonstrations on bundled payments (the Medicare Participating Heart Bypass Center demonstration, the Medicare Cataract Surgery Alternative Payment demonstration, and the Medicare Acute Care Episode (ACE) demonstration) and two gainsharing demonstrations (the Physician Hospital Collaboration demonstration and the 2005 Deficit Reduction Act Medicare Gainsharing Demonstration). [9] Some of these past demonstrations were deemed to be successful; others had mixed results; still others are ongoing.

There are no provisions in the enabling statute that address the duplication of effort within CMS. However, again looking at the Bundled Payment Initiative, Section 3023 of ACA, beginning no later than January 1, 2013, establishes a voluntary pilot program that will pay a single health care entity for all for services delivered during an entire care episode centered on a hospitalization.

[6] Social Security Act Sec. 1115A(b)(3)(B).

[7] Social Security Act Sec. 1115A(b)(4)(A).

[8] Social Security Act Sec. 1115A(b)(4)(B).

[9] See pp. 3-4 of the RFA which can be found here: http://innovations.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Request-for-Applications.pdf

CMMI has deferred implementation of this national pilot program, opting for the increased flexibility of establishing bundled payment models under its separate authority.[10]

**11. The statute requires the Secretary to determine that there is evidence that a model "addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." Could the Secretary implement a model that denies payment for services or benefits currently provided in Medicare if the Secretary deems them "potentially avoidable expenditures"?**

This statutory language references populations where there are "deficits in care" leading to poor clinical outcomes (as well as potentially avoidable expenditures). Although the statutory language would not appear to preclude a model that denies payment for services or currently covered benefits, it is difficult to imagine examples where this approach would benefit a population where deficits in care are already leading to poor clinical outcomes. Still such a determination (where "less" is "more") would likely be up to the Secretary, after consultation with relevant Federal agencies and clinical and analytic experts with expertise in medicine and health care management. One potential example fitting this hypothetical might be if new evidence were to be developed regarding a currently covered service where the service was found to be not efficacious or even potentially harmful.

**13. Could the pilots be used to change benefit design, cost-sharing, co-insurance, and coverage decisions?**

The CMMI's statutory charge is "to test innovative payment and service delivery models to reduce program expenditures [...] while preserving or enhancing the quality of care."[11] Among the models listed in statute are examples that "transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment" and models that include "contracting directly with groups of providers of services and suppliers to promote innovative delivery models, such as through risk-based comprehensive payment or salary-based payment."[12] Such models would likely bring changes in cost-sharing and co-insurance, and possibly benefit design and coverage decisions (if the contracted groups are given such flexibility) as well.

Other examples include "varying payments to physicians ... according to the physician's adherence to appropriateness criteria," "allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State," and "promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or to be involved in establishing the plan of care for the service, when such service is

[10] See p. 2 of the Bundled Payment Initiative FAQs found here: http://innovations.cms.gov/Files/x/Bundled-Payments-for-Care-Improvement-Frequently-Asked-Questions-document-01-31-2012.pdf

[11] Social Security Act Sec. 1115A(a)(1).

[12] Social Security Act Sec. 1115A(b)(2)(B)(i). and 115A(b)(2)(B)(ii).

furnished by a health professional who has the authority to furnish the service under existing State law."[13] Each of these models could conceivably lead to modifications in benefit design, cost-sharing, co-insurance, and coverage decisions.

Again, turning to the specifics of the Bundled Payment Initiative, its RFA addresses the issue of beneficiary protections. Specifically, applicants are informed that beneficiaries in traditional fee-for-service Medicare are entitled to seek care from any provider of their choosing. Nothing in the bundled payment initiative should be construed to limit those choices. All proposals must include a description of the patient notification process, including how it will be implemented and monitored. Moreover, CMS reserves the right to review the status of any award and terminate participation if the awardee restricts access to medically necessary care, among other factors.

### 14. If a pilot aggressively reducing provider payments is implemented nationwide, what is the net effect on beneficiaries?

Because the pilots have yet to be implemented, the actual effect on reducing payments is unknown. However, the statute limits the circumstances under which a pilot could be expanded that is designed to protect against a reduction in quality, thus providing a protection for beneficiaries. The scope of a demonstration project can only be expanded to a national program if the Secretary determines that an expansion would: (1) reduce spending without reducing quality or improve quality without increasing spending; (2) reduce (or not increase) net program spending under applicable titles as certified by the CMS Office of the Actuary (OACT); and (3) not deny or limit coverage.

[13] Social Security Act Sec. 1115A(b)(2)(B)(vi), 1115A(b)(2)(B)(x), and 115A(b)(2)(B)(xvii).