The MODDERN Cures Act of 2011 (HR 3497)
Summary of Diagnostics Provisions

A bill to enact the "Modernizing Our Drug & Diagnostics Evaluation and Regulation Network (MODDERN) Cures Act of 2011" or the "MODDERN Cures Act of 2011" was introduced by Representative Leonard Lance (R-NJ) on November 18, 2011. This bill reflected input of the National Health Council.

Following sections reporting on "findings" and establishing definitions, the bill has two titles, concentrating respectively on diagnostics and on "dormant" therapies. This discussion covers only the diagnostic title. Although the title uses the more general term "diagnostic," it is apparently only concerned with clinical laboratory tests.

TITLE I -- Advancing Diagnostics for Patients

Section 101. Developing a Common Lexicon to Facilitate Progress on Diagnostics

Section 101 would create within the Department of Health and Human Services an Advanced Diagnostics Education Council that would "promote an improved understanding of key concepts related to innovative diagnostics by recommending standard terms and definitions." The Council's membership would be specified to include federal officials, scientists, and representatives of patient advocacy organizations. The Council would solicit input from relevant stakeholders and the public.

The Secretary would be required to publish and disseminate a guide for patients, physicians, providers, payers and policymakers of the terms and definitions recommended by the Council. The Secretary would be required to submit a report to Congress on the duties noted above not later than twelve months after the establishment of the Council.

The Council would terminate after submitting its reports "or later at the discretion of the Secretary."

Section 102. Creating Incentives for Innovative Diagnostics

Subsection (a). Improvements to process for determining fee schedule amounts for new tests.

Subsection (a) would specify the factors to be taken into consideration in rate setting for new clinical laboratory tests by "gapfilling."[1] It would require that, when gapfilling, the Secretary take into account

[1] Gapfilling is one of two processes CMS uses to establish Medicare's payment rate when a new or substantially revised code is added to the Clinical Laboratory Fee Schedule. It is intended for tests that

specified factors: impact on patient care; technical characteristics of the new test and the resources required to develop, validate and perform the test; claims data; laboratory charges to self-pay patients; private insurance rates; recommendations of an advisory panel established by subsection (a)(2); and such other factors as the Secretary may specify.

Subsection (a)(2). Creation of independent advisory panel.

Subsection (a)(2) would require the Secretary to convene an "independent" expert advisory panel with specified membership, from which the Secretary would be required to request information (including technical, clinical and quality information) and recommendations relating to any new clinical laboratory test, whether payment was to be set by gapfilling or crosswalking. The panel would evidently continue indefinitely. It would have 19 members drawn from those with several kinds of specialized expertise; each would serve a six-year term. The Secretary could also include as temporary members individuals with "expertise pertaining to the new test involved." Open meetings would be required.

Subsection (b). Assignment of temporary national codes.

Subsection (b) would require the Secretary to establish a process under which a test manufacturer could apply for assignment of temporary national HCPCS code to "uniquely identify" that test until a permanent code is available. Assignments would be made on a quarterly basis.[2] Public notice of applications would be required. Once a temporary code was established, the Secretary would treat the test as a new test subject to gapfilling or crosswalking.

Subsection (c): Development of further improvements in rate-setting process.
Subsection (c) would require the Secretary to analyze the process for gapfilling to identify changes to improve the accuracy and appropriateness of rates and the transparency and predictability of the process. The Secretary would be required to examine what and how many entities should perform gapfilling, and how to inform the process with expertise and make it transparent and accountable. If the changes were possible under existing law, the Secretary would be required to implement them through regulations. For changes requiring a change in law, the Secretary would be required to transmit recommendations to the Congress.

Subsections (d - e). Definitions and effective date.

This section would be effective on enactment of the bill and would apply with respect to tests assigned a new or substantially revised code on or after January 1, 2013.

Section 103. Promoting the Development of Companion Diagnostics.

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do not have readily comparable tests that can be used as a basis for rate-setting. Crosswalking is the alternative method used for tests where such comparable tests are available.

[2] Codes for lab tests are now routinely assigned on an annual basis. The only area where codes are now assigned on a quarterly basis as result of an application from a sponsor is for pass through payments under the Outpatient Prospective Payment System; in this case, if the product in question does not have a code needed to implement the payment change, a "C" code is established. Note that in this case the codes are necessary to implement a statutory payment policy.

Subsection (a). Determination

The manufacturer or sponsor of a drug or biological product could request that the Secretary determine that a diagnostic test has been developed by or with the participation of the manufacturer or sponsor of the drug or biological; and that the use of the diagnostic test provides for or improves: (1) "the identification of a patient population for which the drug or biological will or will not be used in accord with its approved indications," or (2) "the determination of the most appropriate treatment option for a patient population with the drug or biological in accordance with its approved indications."

The uses in question would be required to be supported by "valid scientific information such as peer-reviewed literature." The Secretary would be required to make the determination in 30 days or less and publish a notice of the determination and any resulting extension in the periods of protection under food and drug statutes, as specified below.

Subsection (b). Applicable extension period.

Defines the applicable extension period: If the test is developed after the drug or biologic has already been approved, the extension would be six months; if development is concurrent, twelve months.

Subsections (c - e). Extension for drugs and biological products.

If the Secretary makes, at request of the manufacturer or sponsor of a drug or biological, the determination described in subsection (a), the Secretary would extend the periods of protection, including patent-related protection, under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act that prevent the marketing of products that would rely upon or reference the drug or biological product in an application by the applicable extension period specified in subsection (b). The extension would be in addition to any period of pediatric exclusivity.

Subsection (f). Limitations.

Extensions under this section could apply not more than twice to the same drug or biological and not more than once with respect to the same indication to be treated by the same drug or biological.