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EXPANDING THE AVAILABILITY OF MEDICARE DATA THROUGH THE QUALIFIED ENTITY PROGRAM: THE MEDICARE ACCESS AND CHIP REAUTHORIZATION ACT OF 2015 (H.R. 2)

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On April 16, 2015, the president signed into law legislation that will significantly broaden the availability of Medicare data. The legislation, the Medicare Access and CHIP Reauthorization Act of 2015, permanently repeals the sustainable growth rate (SGR) formula and reforms the physician payment system. It also includes Section 105, "Expanding Availability of Medicare Data," which makes important changes to the Qualified Entity (QE) program.

This QE provision was carefully crafted over the course of the last three years, and it significantly expands the ways in which Medicare data may be used under the QE program. The language mirrors H.R. 804, the Expanding Availability of Medicare Data Act, stand-alone legislation authored by Representative Paul Ryan (R-WI) and Representative Ron Kind (D-WI). It also contains key elements from S. 679, the Quality Data, Quality Healthcare Act, a stand-alone Senate bill whose original sponsors were Senator Tammy Baldwin (D-WI) and Senator John Thune (R-SD).

Under prior law, the QE program was designed to make Medicare data available for public reporting purposes only. This restriction prevented Medicare data from being used for other important, nonpublic purposes, such as quality improvement and cost reduction purposes. Furthermore, QEs were not allowed to charge for the reports created by combining Medicare data with private claims data. This restriction created significant business model limitations on QEs.

The new legislative provision, which will take one year to go into effect, leaves most aspects of the prior legislation intact and basically expands what the QEs may do with Medicare data. Therefore, it is important to consider the new congressional adjustments within the context of the existing program. It is also important to note that there are limitations on who can become a QE, how the data can be used, and who can access the data. The program also requires certain security and privacy safeguards. Furthermore, there are a number of important regulatory issues that will need to be resolved through Notice and Comment Rulemaking by the U.S. Department of Health and Human Services (HHS).

Below is a summary of the QE program as it exists under current law, an explanation of the key changes made by H.R. 2, and a discussion of next steps in implementing the changes.

The Qualified Entity Program Under Current Law

Section 10332 of the Affordable Care Act amended Section 1874 of the Social Security Act by adding a new subsection (e) requiring standardized extracts of Medicare claims data under Parts A, B, and D to be made available to ''qualified entities" for the evaluation of the performance of providers and suppliers. These QEs are required to combine the data with other non-Medicare claims data and use the combined data to produce **public** reports that measure and evaluate provider performance.

Pursuant to Section 10332, the Centers for Medicare and Medicaid Services (CMS) opened a notice and comment rulemaking process, culminating in final regulations issued on December 7, 2011. These regulations address how the program is operated, and they include rules related to:

- Eligibility criteria for QEs and requirements for the application process
- Operating and governance requirements for QEs
- Privacy and security requirements
- Selection and use of performance measures
- Provider review and correction processes
- Public reporting
- Requirements for the Data Use Agreement with CMS
- Data extraction and dissemination

QE applicants are assessed based on their organizational and governance capabilities; their experience with, and access to, claims data from other sources, and data privacy and security. Since inception, 13 entities have been approved as QEs under the program.

While Section 10332 was an important first step in expanding uses for Medicare data to drive improvement and value in the health care system, as originally written, it is overly restrictive in terms of how QEs can use, analyze, and share the Medicare data they receive. For instance, QEs currently can use only Medicare data for purposes of generating public reports and cannot share Medicare data with downstream users or subscribers or charge a fee for their work product to the extent that it involves Medicare data. These restrictions limit a QE's ability to maximize the utility of its data for providers, patients, purchasers, and other stakeholders.

Expansion of Qualified Entity Program Under H.R. 2

The Medicare Access and CHIP Reauthorization Act makes a number of important changes to current law, and gives QEs more flexibility to use data for purposes other than public performance reports. Specifically, the legislation makes the following changes, which would be effective July 1, 2016:

- *Allow QEs to provide or sell* analyses *to downstream "authorized users."* – A QE will be able to use combined data to conduct "additional nonpublic analyses," as determined appropriate by the secretary, and provide or sell those analyses to certain "authorized users" for nonpublic use. The list of authorized users includes (1) a provider of services (2) a supplier (3) an employer who will use the analyses for only purposes of providing health insurance to its employees and retirees (4) a health insurance issuer that is providing the QE with data (5) a medical society or hospital association and (6) any other entity that is approved by the secretary. The analyses could not contain any information that individually identifies patients, except where the information relates to patients of the providers and suppliers who are receiving the analyses. Authorized users are prohibited from using the analyses for marketing purposes.

- *Allow QEs to provide or sell access to* combined data *to a subset of authorized users* – A QE will also be able to provide or sell combined data to a subset of authorized users for nonpublic use, including for purposes of assisting providers and suppliers in developing and participating in quality and patient care improvement activities, including developing new models of care. Authorized recipients of the combined data include (1) a provider of services (2) a supplier and (3) a medical society or hospital association. Employers and health insurance issuers are not allowed to access the combined data from the QE. The data could not contain any information that individually identifies patients, except where the information relates to patients of the providers and suppliers who are receiving the data. QEs and authorized users must enter into a data -use agreement (DUA), which must contain privacy and security requirements, and, as determined appropriate by the secretary, any prohibitions on using data to link to other individually identifiable sources of information. Authorized users are prohibited from using the data for marketing purposes.

- *Allow QEs to provide, at no charge*, Medicare-only claims data *to a subset of authorized users* – A QE may provide, at no charge, Medicare-only claims data to (1) providers (2) suppliers and (3) medical societies or hospital associations. The data may not contain any information that individually identifies patients, except where the information relates to patients of the providers and suppliers who are receiving the data. QEs and authorized users must enter into a DUA, which must contain privacy and security requirements, and, as determined appropriate by the secretary, any prohibitions on using data to link to other individually identifiable sources of information. Authorized users would be prohibited from using the data for marketing purposes.

- *Allow providers and suppliers who are authorized users to redisclose analyses and data for nonpublic uses* – In general, authorized users would be prohibited from redisclosing or making public any analyses or data provided to them (or any analyses the user generates from data provided to them). However, providers and suppliers who are authorized users may, as determined appropriate by the secretary, redisclose analyses or data for purposes of performance improvement and care coordination activities, so long as the analyses or data are not made public.

- *Require QEs to offer providers and suppliers an opportunity to review* – Prior to providing or selling an analysis to an authorized user, where the analysis identifies a provider or supplier who is not being provided with or sold the analysis, a QE must offer the provider or supplier an opportunity to appeal and correct errors.

- *Assess penalties for breach of DUA* – The Secretary will have the authority to assess a penalty on the QE in the event that the QE breaches its DUA with CMS **or** where the authorized user breaches its DUA with the QE. The assessment would be an amount up to $100 for each individual Medicare beneficiary whose data was disclosed pursuant to the DUA.

- *Require annual reporting by QEs* – QEs providing or selling nonpublic analyses or data will be required to submit annually to the secretary a report that includes (1) a summary of the analyses provided or sold and the total amount of fees received (2) a description of the topics and purposes of such analyses (3) information on the entities who receive actual data, including the uses of the data and the fees generated; and (4) other information as required by the secretary.

Next Steps: Implementation Through Notice –and- Comment Rulemaking

The changes to the QE program become effective on July 1, 2016. Prior to that time, HHS will need to revise its regulations to implement the changes, and it will undertake a notice-and-comment rulemaking process to gather stakeholder input. Some of the major areas ripe for rulemaking include:

- *Additional analyses* – The secretary will need to determine what it means for a QE to conduct "additional nonpublic analyses."

- *Nonpublic use* – The secretary will need to define what constitutes a permissible "nonpublic use."

- *Data use agreement* – The secretary will need to determine what privacy and security requirements must be embedded in the data use agreement between the QE and the authorized user who is getting access to the data.

- *Review and correction process* – The legislation requires QEs to have a review and correction process open to all providers and suppliers who are identified in a nonpublic analysis if they are not also the recipients of the analysis. This requirement is already in place under current regulations with respect to public reports.

- *Additional authorized users* – The secretary will have to set up a process for approving additional users not otherwise identified in the legislation who will be allowed to receive analyses (the legislation prevents these approved additional users from getting access to the combined data).

In addition to these key areas that relate to newly expanded nonpublic uses, it is possible that HHS could consider revisiting other issues not directly impacted by the legislation.

Contact Information

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