



**American Hospital
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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–5061–P, Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on expanding uses of Medicare data as it relates to the Qualified Entity Program.

Section 10332 of the Affordable Care Act (ACA) amended section 1874 of the Social Security Act by adding a new subsection requiring the Department of Health and Human Services (HHS) Secretary to make available standardized extracts of Medicare claims data under parts A, B and D to “qualified entities” (QE) for the evaluation of the performance of providers of services and suppliers. Approved QEs are required to produce and make publicly available reports on individual providers and suppliers in an aggregate form. Currently, 14 QEs have been approved by CMS, of which three will publicly report provider performance in all 50 states and the District of Columbia. Under section 105 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, QEs will be allowed to conduct additional non-public analyses and provide or sell these analyses to authorized users for non-public use, which includes assisting providers and suppliers to develop and participate in quality and patient care improvement activities, including developing new models of care. This provision will take effect July 1, 2016.

The AHA agrees with several of the proposals set forth by CMS in its proposed rule and applauds the agency for publishing a comprehensive proposed rule on expanding uses of Medicare data by QEs. Following are our detailed comments on select areas in the rule.



ADDITIONAL ANALYSES

CMS proposes to add, at §401.703(q), a definition of “combined data” as a set of CMS claims data provided under subpart G of 42 CFR part 401 (76 FR 76542) that are combined with claims data from at least one other provider-identifiable or supplier-identifiable claims data source for which a QE has full data usage rights. CMS is not proposing to establish a minimum amount of data from other sources that need to be included in the combined data set as CMS believes that it would be difficult to establish a threshold given the variability in the analyses that the QEs might conduct. CMS seeks comments on this proposal and asks for possible alternatives or options.

While the AHA acknowledges that it might be difficult to establish a minimum standard for the amount of claims data from other sources that the QE should include in a combined data set, we urge CMS to require each QE to make public a list of the Medicare claims datasets that it received from CMS, as well as the datasets that it intends to combine with the Medicare claims data. This list should include a description of the dataset, source of the data, time period for which the data are available, geography/region pertaining to the dataset and the approximate number of beneficiaries included. The list also should include the measures that the QE intends to publish with each dataset along with the measure methodology. CMS should consider publishing this public inventory of the datasets available to each QE at <https://www.qemedicaredata.org/>. This would ensure that while CMS is not requiring a minimum standard for the non-Medicare portion of the combined dataset, there is a level of transparency in the QE program that would allow potential authorized users to determine whether they should request or purchase non-public analyses based on either the Medicare-only or the combined data.

LIMITATIONS ON HEALTH INSURANCE ISSUER AS RECIPIENT

MACRA mandates that a QE may not provide or sell non-public analyses to a health insurance issuer unless the issuer provides the QE with claims data, but does not specify a minimum amount of data that the issuer must provide to the QE. However, CMS is proposing at §401.716(b)(1) to limit a QE to providing or selling non-public analyses to an issuer only after it has provided the QE with claims data that represent a majority of the issuer’s covered lives in the geographic region and during the time frame covered by the non-public analyses that the issuer has requested. For example, an issuer who requests non-public analyses using combined data in Minnesota for the first six months of 2015 would need to provide the QE with data on at least 50 percent of the issuer’s covered lives in Minnesota for that same time period. CMS seeks comments on whether the threshold of a majority of the issuer’s covered lives is too high or too low, and asks for alternative suggestions.

The AHA believes that the threshold of a majority of the issuer’s covered lives is too low. Instead, CMS should require a QE to provide or sell non-public analyses to an issuer only after it has provided the QE with data on all of its covered lives for the geographic region and during the time frame of the non-public analyses requested by the issuer. Providers and suppliers would be permitted to use the non-public analyses based on either the combined or Medicare-only claims datasets for quality assessment and improvement activities, care coordination activities, including the review of provider or supplier performance, and/or for

fraud, waste, and abuse detection and compliance purposes. Granting the QE access to 100 percent of the issuer's covered lives in the same region and during the time period for which the analyses are requested would allow for a more complete analysis of the beneficiaries using the combined data and allow for better care coordination and quality assessment and improvement activities based on these analyses.

DE-IDENTIFICATION OF BENEFICIARIES AND DEFINITION OF PATIENT

CMS recognizes that providers and suppliers who receive non-public analyses might require individually identifiable information such as name, age, gender, date of birth, etc., in order to work with other providers to better coordinate or improve care. CMS proposes, at §401.716(b)(2), to limit the provision or sale of non-public analyses that individually identify a beneficiary to providers or suppliers with whom the individual has "established a patient relationship." CMS proposes, at §401.703(r), to define a patient as an individual "who has visited the provider or supplier for a face-to-face or telehealth appointment at least once in the past 12 months." CMS states that this definition is similar to the one used in the Medicare Shared Savings Program where beneficiaries are assigned to Accountable Care Organizations (ACO) based on services delivered in the prior 12 months. CMS also believes that this definition would allow providers and suppliers to receive information only on patients they are actively treating. CMS seeks comment on this definition.

The AHA believes that the 12-month period is insufficient for purposes of quality assessment/improvement and care coordination activities. Instead, CMS should define a patient as an individual "who has visited the provider or supplier for a face-to-face or telehealth appointment at least once *during the time period for which the analysis is being conducted.*" A 12-month cutoff is used in the Medicare Shared Savings Program for purposes of assigning beneficiaries to providers in an ACO; hence, imposing a time frame is reasonable. However, if providers and suppliers will be permitted to use the non-public analyses to improve quality assessment/improvement and care coordination activities, it is possible that they may need access to identifiable patient information even if they have not had a face-to-face or telehealth encounter with the patient in the prior 12-month period. We urge CMS to consider expanding the time period to the duration for which the analyses are being performed. For example, if the QE is using two years of data for purposes of the analysis, then the provider or supplier should be allowed access to individually identifiable information on any patient whom it has seen in the two-year period.

LIMITATIONS ON THE QE REGARDING DATA DISCLOSURE AND LINKING OF PATIENT INFORMATION

CMS acknowledges that while it can impose requirements on the QE it does not have the authority to impose legally enforceable requirements on authorized users. Therefore, the agency must rely on the QE to do so through the use of a data use agreement (DUA) between the QE and the authorized user, which CMS distinguishes from the CMS DUA entered into between CMS and the QE. CMS proposes to require QEs to contractually bar the downstream recipients from linking the combined data, Medicare-only data, and/or non-public analyses that contain patient

identifiable data and/or any derivative data to any other identifiable source of information, except for those providers or suppliers who receive identifiable information limited to their own patients. CMS seeks comment on this proposed requirement.

The AHA supports the ability of providers and suppliers who receive identifiable information limited to their own patients to link the combined data, Medicare-only data, and/or non-public analyses that contain patient identifiable data and/or any derivative data to any other identifiable source of information. Such linking is essential to allow providers and suppliers to conduct quality assessment/improvement and care coordination activities. However, the AHA also urges CMS to explicitly grant any business associates of providers and suppliers, acting on their behalf, the ability to link the different kinds of data and analyses specified above to other identifiable sources of information.

AUTHORIZED USERS: DEFINITION OF HOSPITAL ASSOCIATION

The AHA is concerned that the definition of hospital association as proposed by CMS is too narrow, and we urge CMS to expand the definition, as described below.

Section 105(a)(9)(A) of MACRA defines an “authorized user” as: (i) a provider of services; (ii) a supplier; (iii) an employer; (iv) a health insurance issuer; (v) a medical society or hospital association; and (vi) any entity not described above that the Secretary approves. CMS proposes, at §401.703(j), to define authorized user in a similar manner as defined in MACRA with two additions, per the authority granted it under clause (vi): a health care provider and/or supplier association; and a state agency. Furthermore, CMS defines a hospital association, at §401.703(n), as “a nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national or state level and whose membership is comprised of a majority of hospitals and health systems.” CMS also proposes to limit the definition of hospital association to the national or state level, stating that state hospital associations are often affiliated with local hospital associations that perform similar functions and hence any use of the data by state hospital associations could benefit the local associations as well.

The AHA urges CMS to amend its definition of “hospital association” at §401.703(n) to read:

“Hospital association means a nonprofit organization or association, whose membership is comprised of a majority of hospitals and health systems, that provides unified representation and advocacy for hospitals or health systems at a national, state or local level, or any of its affiliated entities.”

As an example of an affiliated entity that clearly should be included in the definition of hospital association, the Health Research & Educational Trust (HRET) is the not-for-profit research and education affiliate of the AHA. HRET’s applied research seeks to create new knowledge, tools and assistance in improving the delivery of health care by providers and practitioners within the communities they serve. HRET’s work on multiple, major national clinical improvement initiatives – such as CMS’s Hospital Engagement Network and several Agency for Healthcare

Research and Quality national programs – has contributed to better care for more than 100,000 patients and resulted in \$1 billion in cost savings through the prevention of infections, other adverse events and readmissions. It also was instrumental in designing and launching the National Call to Action to Eliminate Health Care Disparities in 2011, followed by the launch of the #123forEquity Pledge campaign in 2015. Furthermore, HRET has led the AHA's efforts through the *Hospitals in Pursuit of Excellence* initiative to develop new tools and resources that have helped the field focus on and improve its performance. HRET has clearly made significant and lasting contributions that have helped take the field to new places in improving quality, enhancing diversity and reducing disparities.

CMS notes that hospital associations serve as the consensus voice of their members in matters related to their facilities, quality and affordability of services, and other issues regarding the provision of health care. As demonstrated above, HRET clearly aids the AHA's efforts in helping the field achieve better quality assessment/improvement and care coordination. As such, we urge CMS to expand its definition of hospital association to include entities such as HRET that are affiliated with hospital associations.

In addition, state hospital associations often have separate quality improvement and patient safety arms that assist the state association in such activities. Also, there are local hospital associations that, while affiliated with their state hospital associations in some quality and patient safety initiatives, might partner with other organizations in other such initiatives, and hence might benefit from receiving the non-public analyses, combined data or Medicare-only data, directly from the QE. CMS also should include these entities and associations in its definition.

ADDITIONAL DATA

Section 105(c) of MACRA gives the HHS Secretary the discretion to provide additional data to QEs, including standardized extracts of claims data under titles XIX (Medicaid) and XXI (the Children's Health Insurance Program (CHIP)) for one or more specified geographic areas and time periods that the QE may request. Medicare is a national program administered by CMS and guidelines about claims submission and data cleaning are consistent across the program. Medicaid and CHIP are state-run programs where states submit data to CMS. Furthermore, each state's Medicaid agency collects enrollment and claims data for persons enrolled in Medicaid and CHIP via the state's Medicaid Management Information System (MMIS). The federal government partners with each state to monitor health care delivery and payment on a national level. In order to facilitate this, the MMIS data are converted into a national standard and submitted to CMS via the Medicaid and CHIP Statistical Information System (MSIS). CMS states that the MSIS enrollment and claims data are reported to CMS on a quarterly basis only and are challenging to use because of varying time periods. As a result, CMS proposes not to expand the data available to QEs and believes that QEs would be better off requesting Medicaid and/or CHIP data directly from the state Medicaid agencies because of the difficulties in using the MSIS data and the variation in time periods.

The AHA urges CMS to consider expanding the data available to QEs to include standardized extracts of claims data under titles XIX (Medicaid) and XXI (the Children's

Health Insurance Program (CHIP) for one or more specified geographic areas and time periods that the QE may request. QEs already undergo an application process with CMS to receive standardized extracts of the Medicare claims data under parts A, B and D. If CMS also allows them access to the MSIS data (or whatever other format the Medicaid and/or CHIP data may be available), it will obviate the need for additional application processes the QEs may have to undergo with one or more state agencies, particularly since the data in MSIS have already been converted into a national standard. Furthermore, CMS states that the data are challenging to use because they represent a mixture of time periods. However, providers submit Medicare claims and cost reports at varying time intervals, and CMS makes these data available.

Furthermore, section 2602 of the ACA established the Federal Coordinated Health Care Office within CMS (also known as the Medicare-Medicaid Coordination Office) in order to improve care coordination of “dual eligible” beneficiaries who are enrolled in both Medicare and Medicaid. The goal of the office is to ensure that dual eligibles have full access to high quality and seamless health care in a cost-effective manner. The Medicare-Medicaid Coordination Office works with both the Medicaid and Medicare programs to align and coordinate benefits between the two programs effectively and efficiently. The office partners with states to develop new models of care as well as improve the way dual eligibles receive health care. One of the goals of the Medicare-Medicaid Coordination Office presented in the ACA is “[i]mproving the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs.” In order for providers and suppliers to participate in quality improvement and care coordination of dual eligibles, it is essential for them to have access to the Medicaid and CHIP data in a cost-effective and efficient manner. This includes not having to apply to the states separately to obtain these data, but rather having access to the data through the QE program. This also ensures that the QEs receive the Medicare and Medicaid and/or CHIP data from a single source, resulting in a more efficient and less burdensome process.

REGULATORY IMPACT ANALYSIS

Section 1102(b) of the Social Security Act requires CMS to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. The RIA must conform to the provisions of section 603 of the Regulatory Flexibility Act. CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. CMS anticipates that most QEs would focus their performance evaluation efforts on metropolitan areas where the majority of health services are provided. As a result, the HHS Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

The AHA believes that CMS has underestimated the overall regulatory impact of this proposed rule. Three of the QEs (the Health Care Cost Institute, Amino and OptumLabs) have been approved to receive national data and CMS’s [website](#) on the QE program shows that these QEs plan to publicly report provider performance for “all 50 states and the District of Columbia.” At this time it is not publicly known whether the QEs plan to release reports that will affect all hospitals in the nation or just hospitals in metropolitan areas as CMS anticipates. In

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2014, there were approximately 4,900 community hospitals in the nation of which 38 percent were rural and 62 percent were urban. Approximately 1,500 rural hospitals (81 percent of all rural hospitals) had fewer than 100 beds. Should the QEs choose to release non-public analyses for all of the hospitals in the nation and not just in metropolitan areas, such a release would significantly impact a substantial number of rural hospitals. **We urge CMS to reconsider its assumption that all 1,500 small rural hospitals would not be impacted by this rule and prepare a RIA to be published in the final rule. If CMS chooses not to prepare a RIA in the final rule it should provide a more detailed explanation of its assumptions.**

IMPACT ON HEALTH CARE PROVIDERS AND SUPPLIERS

CMS has assumed that it would take providers and suppliers, on average, three hours to review the non-public analyses generated by the QEs and an average of seven hours to prepare and submit appeal requests. CMS also has assumed that each QE will, on average, produce non-public analyses that in total would include information on 7,500 health care providers and suppliers (of which 95 percent would be physicians). Based on these assumptions, CMS has estimated a total impact on providers and suppliers of approximately \$30 million.

The AHA believes that CMS has underestimated the total impact on providers and suppliers. While recognizing that CMS's assumption of three hours covers a range of one or two hours for some providers and a significant amount of time for other providers, an assumption of just three hours on average to review non-public analyses appears too low. In addition, even though the non-public analyses might be based on the same underlying data used for the public performance reports, it is reasonable to assume that the non-public analyses requested by providers and suppliers for their own quality assessment/improvement and care coordination efforts might actually be more complicated than the analyses conducted for the public performance reports used to merely report on mainly standard measures. And it might take even longer for providers and suppliers to review the non-public analyses if they contain data on a significant number of measures. Including the fact that CMS has excluded a large number of rural hospitals that could potentially be impacted, the \$30 million impact on providers and suppliers appears too low. **We urge CMS to revisit its assumptions regarding the impact on providers and suppliers.**

Thank you again for the opportunity to comment. If you have any questions, please contact me or Christopher Vaz, director of health analytics and policy, at (202) 626-2276 or cvaz@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President