



March 29, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Mr. Slavitt:

On behalf of AMGA, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) proposed rule titled, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities." AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one-in-three Americans. Through AMGA Analytics, our collaborative for improving population health through comparative clinical analytics, AMGA is uniquely positioned to analyze administrative claims data and clinical records to identify and help implement clinical practice improvements. AMGA is therefore supportive of efforts to expand the use of data for healthcare improvement purposes and offers these comments on the Qualified Entity program to further that goal.

AMGA recommends that CMS revise its proposed combined data definition, expand the definition of authorized user, finalize the proposed de-identification standard, authorize broader use of re-disclosures, and include Medicaid data in the Qualified Entity program.

Revise Combined Data Definition

CMS is proposing a definition of combined data that is too limited. By restricting the definition to claims data only, CMS is missing an opportunity to develop a more robust Qualified Entity program. In other aspects of the Medicare program, CMS has recognized the need to include clinical data. For example, in its Advance Notice of Methodological Changes for Calendar Year 2017 Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter, CMS proposed to implement a new analytical adjustment, termed the Categorical Adjustment Index (CAI), which would add or subtract from a contract's Overall and/or Summary Star Rating to adjust for the average within-contract proportion of dual-eligible, Low Income Subsidy (LIS) and disabled beneficiaries. In context of the Medicare Advantage (MA) program, including this demographic data will capture plan performance more accurately. By expanding the definition of Combined Data for the Qualified Entity program to include similar social-economic and demographic data, CMS could foster a more complete understanding of clinical outcomes and any disparities in care that need to be addressed. AMGA recommends that CMS revise the proposed definition at 42 CFR §401.703(q) to include clinical, consumer, socio-demographic data, and other data that will promote quality improvement.

Expand Authorized User Definition

The Medicare Access and CHIP Reauthorization Act (MACRA) provides the Secretary of the Department of Health and Human Services with the discretion to expand the definition of Authorized User beyond those entities

that are named in the statutory definition. AMGA recommends that CMS include this authority in its regulations at §401.703(j). In addition, CMS should recognize that its proposed definition, which simply restates the MACRA language, would exclude a number of entities that currently are engaged in healthcare improvement activities and have competently and securely used de-identified healthcare data for research purposes. Qualified entities should be free to enter into Data Use Agreements (DUA) with any research entity.

Finalize De-Identification Standard

AMGA recommends that CMS finalize its proposal that all non-public analyses must be de-identified based on the standards in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 164.514(b). This standard has proven effective and implementing a competing standard to govern the Qualified Entity program is unnecessary.

Authorize Broader Re-Disclosures

CMS has proposed requiring Qualified Entities to contractually limit re-disclosures of beneficiary de-identified non-public analysis or any derivative data except to the extent the disclosure is required by law. AMGA contends this proposal is too restrictive and would hinder the quality improvement activities envisioned by the Qualified Entity program. While we appreciate and share CMS' concern to protect against the disclosure of identifiable beneficiary information, once the data is de-identified, the data should be broadly available for research activities.

Include Medicaid Data

AMGA recommends that CMS include Medicaid data in the Qualified Entity program. The Medicaid Statistical Information System, known as Transformed-MSIS (T-MSIS), will be an appropriate resource for the Qualified Entity program. This would facilitate a broader understanding of the dual-eligible population and eliminate the need for a Qualified Entity to contract with each individual state.

Conclusion

AMGA appreciates the opportunity to submit comments on the proposed rule. Properly used and protected, a healthcare data set that includes claims records, clinical data and demographic information has the potential to improve patient care and outcomes across the healthcare system. If you have any questions, please feel free to contact AMGA's Darryl M. Drevna, director of regulatory and public policy at ddrevna@amga.org or 703-838-0033 ext. 339.

Sincerely,



Donald W. Fisher, Ph.D., CAE
President and CEO