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AHIMA
American Health Information Management Association®

March 29, 2016

Acting Administrator Andy Slavitt
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, (CMS-5061-P)

VIA E-MAIL

Dear Administrator Slavitt:

Thank you for the opportunity to submit comments on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities proposed rule.

AHIMA is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents over 103,000 health information management professionals dedicated to effective health information management, information governance, and applied informatics. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and providers. AHIMA provides leadership through education and workforce development, as well as thought leadership in continuing HIM research and applied management for health information analytics.

In general, we support the approach taken here by the Centers for Medicare and Medicaid Services (CMS) regarding the requirements in the non-public analyses agreement. Furthermore, we believe the privacy and security requirements for the Qualified Entity Data Use Agreement (QE DUA) are appropriate and adequate as well as sufficiently aligned with the privacy and security requirements under the Health Insurance Portability and Accountability Act (HIPAA). AHIMA recommends that CMS continue to ensure that the use of data in the qualified entity program aligns with those outlined in the HIPAA statute in order to foster beneficiary trust and support of the Qualified Entity program.

Although the proposed rule covers a number of topics, we have focused our comments below on several issues that AHIMA believes are critical to ensuring the success of the Qualified Entity Program.

Qualified Entity Data Use Agreement (QE DUA)

AHIMA agrees with the proposed rule that authorized users should not be able to re-disclose or make public any combined data, Medicare claims data and/or non-public analyses that contain identifiable data and/or any derivative data subject to the QE DUA except as provided under the QE DUA. AHIMA also

supports the proposal that would require the qualified entity to use the QE DUA to limit providers' and suppliers' re-disclosures to a covered entity pursuant to 45 CFR 164.506(c)(4)(i), 164.502(e)(1) or when re-disclosure is required by law.

AHIMA believes that the proposed re-disclosure requirements strike the right balance in ensuring that the data is appropriately managed, maintained, used and disclosed. To allow the re-disclosure requirements to be more restrictive would hinder the ability of providers and/or suppliers to focus on quality assessment and improvement. At the same time, allowing for broader re-disclosure could potentially jeopardize beneficiary privacy and security, undermining beneficiary trust and support of the program.

AHIMA also agrees with the requirement in the proposed rule that the QE DUA agreement prohibit authorized users from linking re-disclosed combined data, Medicare claims data, and/or non-public analyses that contain identifiable data and/or any derivative data to other identifiable sources of information unless a provider and/or supplier receives the identifiable information about their/its own patients. Today, increasingly different types of health data are being collected including data from medical devices, clinical trials, clinical registries, public health surveillance data, genomic data and other "omics" related data.[1] The volume of health data is only expected to grow exponentially in the future. It is projected that an estimated 50 billion connected devices will be available globally by 2020—approximately six devices per person, many of which will have the ability to collect usable data.[2] As different types of health data continue to proliferate, the ability to link different types of data (identifiable or otherwise) could potentially expose sensitive patient information. Consequently, we believe that this requirement sufficiently protects the privacy and security of the data when it is provided or sold to downstream users.

Annual Reporting Requirements

AHIMA supports the annual reporting requirements for the non-public analyses and for data under the proposed rule. However, we recommend that these reports be made publicly available (preferably online) to provide greater transparency to the public as to what authorized users are provided or sold such non-public analyses and/or data.

We thank you for the opportunity to submit comments on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities proposed rule. We look forward to working with CMS to ensuring a successful and robust Qualified Entity program. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Senior Director, Federal Relations, at lauren.riplinger@ahima.org and (202) 839-1218, or Pamela Lane, Vice President, Policy and Government Relations, at pamela.lane@ahima.org and (312) 233-1511.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
Chief Executive Officer

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[1] Agency for Healthcare Research and Quality. *Data for Individual Health* (Publication No. 15-0006-EF). Washington D.C.: AHRQ, 2014.

[2] Topol, Eric., Steinhubl, Steven., and Ali Torkamani. "Digital Medical Tools and Sensors." *Journal of American Medical Association,* 313, no. 4 (2015): 353-354.