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June 2, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Berwick:

The American Health Information Management Association (AHIMA) is pleased to submit to you comments and recommendations on the notice of proposed rulemaking published in the *Federal Register* Thursday, April 7, 2011 regarding the Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center [76FR19528].

AHIMA is a not-for-profit professional association representing more than 61,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, and reporting data vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most. We respectfully submit our comments as our members are and will continue to be active participants in the implementation, maintenance, and compliance of the Accountable Care Organization (ACO) program.

If AHIMA can provide further information or if there are any questions regarding our recommendations, please contact me at (202) 659-9440 or allison.viola@ahima.org, or Dan Rode, vice president, policy and government relations, at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

A rectangular box containing a handwritten signature in cursive script that reads "Allison Viola".

Allison Viola, MBA, RHIA
Director, Federal Relations

cc: Dan Rode, MBA, CHPS, FHFMA, Vice President, Policy and Government Relations

Subpart B—Shared Savings Program Requirements
§ 425.5 Eligibility and governance requirements

During the initial stages of the ACO program, AHIMA recommends participation should be limited to those participants specifically identified in the statute on page 76FR19537 to promote clarity during the program's infancy. The implementation of this program demands significant changes to health care delivery, data sharing, and data integration among providers and disparate groups. Therefore, providing clear guidance on who can participate reduces confusion and uncertainty within the provider and hospital community.

The notice of proposed rulemaking (NPRM) discusses the option of restricting eligibility to only those ACO professionals providing care services. We agree with the notion that by coordinating with specialists to whom the beneficiary has been referred, primary care providers can reduce unnecessary repetition of laboratory testing and imaging limiting the number of avoidable admissions. During these situations, it is critical to enable the sharing of patient health information to ensure a continuum of care that is based upon the data that has been captured during primary care services and beyond.

As CMS considers legal structure options for ACOs, as discussed on page 76FR19540, AHIMA recommends that verbiage be added to include when an ACO operates in multiple states such as in the border areas. The ACO attests to operate under each state's rules rather than a blend of multiple states' rules for all business and other operational functions (i.e. including health information management, release of information, privacy/confidentiality, data quality, etc.). AHIMA has historically supported leveraging a uniform approach toward privacy and security processes nationwide to ensure administrative simplicity. We continue to support this approach as we believe this will assist in reducing burden.

Considering the leadership and management structure proposed for ACOs as described on page 76FR19542, AHIMA encourages CMS to introduce an additional factor to establish a dedicated health information management leadership in the ACO: A Credentialed Health Information Management Professional (e.g. RHIA, RHIT, CHPS, etc.). We suggest recommended duties to include "the dedicated health information management professional would have a proven ability to ensure the privacy, security, and integrity of data is maintained." RATIONALE: 1. To maintain compliance with existing federal rules and regulations, HIPAA, HITECH, ARRA, etc. 2. Will assist in meeting the criteria outlined for quality management in this proposed rule.

To be consistent with established federal rules AHIMA recommends "*personal representative*" be included anywhere in this proposed rule where patients and their families are referenced. As cited from the NPRM on page 76FR19547, "The term 'patient engagement' is the active participation of patients and their families in the process of making medical decisions." For example, .."active participation of patients or their personal representative and their families in the process of making medical decisions." Many Medicare beneficiaries have diseases or symptoms that require a caregiver be fully engaged with their overall care, which includes understanding the treatments they receive and the requirements to support them during recovery. As noted by the Alzheimer's Association, "In 2010, 14.9 million family and friends provided 17

billion hours of unpaid care to those with Alzheimer's and other dementias.”¹ This briefly demonstrates the environment of personal representatives that are actively participating in the care and provision of support to the Medicare population.

Regarding the proposed definition for patient-centeredness criteria as described on page 76FR19547, AHIMA recommends inserting the term “confidentiality” to read, “A patient-centered, or person-centered, orientation could be defined as care that incorporates the values (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, *confidentiality*, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care.”

On page 76FR19548 the NPRM discusses the requirement for ACOs to develop written standards for beneficiary access and communication and a process to access medical records. AHIMA applauds CMS for recognizing and acknowledging the need for this action to occur, however we recommend CMS leverage the objectives that have been developed and recommended by the Health Information Technology Policy Committee Meaningful Use workgroup to enable patient access to their health information. We understand the objectives for Stage 2 of the Meaningful Use program is yet to be determined, but CMS would benefit by leveraging the good work that has been accomplished in future stages of defining patient access. We believe this will reduce the burden and duplication of the ACO and the health information management community to support potentially differing policies for patient's access to their health information.

In light of the recent NPRM released on Tuesday, May 31, 2011 entitled, “HIPAA Privacy Rule Accounting of Disclosures under the HITECH Act” [76FR31426] AHIMA is concerned regarding the disclosure of treatment, payment, and operations (TPO) within an ACO. We encourage CMS to actively consider both initiatives and align them for the improvement of sharing data for quality patient care.

§ 425.19 Data sharing with ACOs

Regarding the sharing of aggregate data beginning on page 76FR19555 which highlights beneficiary use of health care services, the proposed regulation does not clearly state the structure or format of the aggregate data being submitted. AHIMA strongly recommends that it be submitted as discrete data, rather than a summary, a report, a PDF, or other form that is not discrete and cannot be queried. While reporting requirements continue to increase, the need for efficient access to data and secondary uses of the data also persist; thus placing additional burden on resources. By maintaining health information in discrete data element formats, the ability to mine and query this data greatly improves reporting capability. In addition, while the data is aggregate and non-identifiable, it should have enough associated information to allow the ACO to sort and mine the data to drill down to non PHI details in order to identify trends and make improvement decisions (specific physician, location, etc...).

In general, AHIMA supports the proposed data set for Quality Performance scores; however, we request further clarification regarding the claims data related to patient non-compliance. If

clinical data is available for different patient compliance measures, that should be made available. For example, patient non-compliance with taking their prescription medications will impact the ACOs efforts to reduce costs.

We encourage CMS to give consideration of patient engagement, responsibility, and accountability for their treatment while participating within an ACO. We believe this model of care encourages patients to become more engaged and they should bear some responsibility. The use of V-Codes may provide an option for tracking non-compliance; however we do not believe in establishing an adversarial relationship between the patient and provider. This could create an opportunity for continued focus on the relationship and education to support compliance and increased savings. Factors to consider are:

- Non-filled medications
- AMA discharges
- Letter from provider about separating from non-compliant patients.

On page 76FR19555, the NPRM proposes developing aggregate metrics on populations and subpopulations. AHIMA believes additional subpopulations are needed. We recommend allowing ACOs to request different or additional subpopulations and within this data should be additional elements including age category and race. We also recommend adding obesity, MRSA and/or VRE history, infectious disease including hepatitis, HIV, veterans, dual diagnosis, behavioral health, well patient population, OB/Women's Health, and complications due to diabetes.

In addition, we recommend developing aggregated metrics on the assigned beneficiary population and beneficiary utilization data at the beginning of the agreement period based on historical data used to calculate the benchmark. This information will serve as the baseline for ACOs and allowing them the ability to demonstrate meaningful change over a period of time. The proposed rule does not clearly state what specific metrics for historical data will be provided at the beginning of the agreement. We propose including these data in conjunction with the yearly financial and quality performance reports.

AHIMA believes ACOs would benefit from understanding which of their fee-for-service beneficiaries were used to generate the aggregated data reports through identifying historically assigned beneficiaries. First, the ACO providers could use the information to identify the beneficiaries, review their records, and for proactive care coordination efforts, and track their progress against defined performance measures. Second, knowing individuals who have been assigned in the past would help the ACO participants to identify individuals who may benefit from improved care coordination strategies moving forward. We also suggest indicating which, if any, the subpopulations this beneficiary was counted in along with race and ethnicity. AHIMA further recommends in addition to the aggregate data noted in the proposed rule, that CMS also supply national benchmarks so the ACOs can compare their performance to these national benchmarks.

AHIMA supports the statements regarding the HIPAA and the Privacy Act of 1974 as stated on page 76FR19556. We agree the data sharing as proposed is appropriately supported by the two

regulations provided that the covered entities have business associate agreements (BAAs) in place with ACOs that are not themselves covered entities. We strongly recommend CMS closely review the NPRM released on Tuesday, May 31, 2011 entitled, “*HIPAA Privacy Rule Accounting of Disclosures under the HITECH Act*” [76FR31426] as the impact of the proposal on ACOs could result in unintended consequences.

AHIMA supports the approach if an ACO does not choose to request beneficiary identifiable claims data from CMS at the time of its application as described on page 76FR19557, it will be required to submit a formal request for data during the agreement period that includes a description of how it intends to use the requested data for the purposes noted previously.

AHIMA suggests providing additional guidance and clarification on whether a data use agreement (DUA) may or may not prevent the ACO from contracting and having a BAA and the ability to use the data as a service for the ACO (trending, identifying areas to focus), as discussed on page 76FR19557. According to the proposed rule, “*Under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO.*” We also recommend CMS provide clarification regarding the process to reach a decision of non-compliance and what the process will be in communicating this to the ACO. AHIMA recommends clarifying the termination time period and when an ACO has the opportunity to re-apply.

On page 76FR19557, the proposed rule states “*We propose to make compliance with the DUA a condition of the ACO’s participation in the Shared Savings Program — noncompliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to termination from the Shared Savings Program or additional sanctions and penalties available under the law.*” AHIMA suggests further clarification on determining non-compliance, and if the ACO would be investigated in order to determine a conclusion. Factors to consider are:

- Would this be flagged by a complaint by a beneficiary, data breach, or other methods?
- Defining how it will be determined if a breach or other violation is that of a partner versus the ACO entity?
- Defining the process to communicate to the ACO regarding termination or non-compliance.

AHIMA recommends Parts A and B data be available for all patient visits, not just primary care physicians, in response to CMS’ proposal to make Part A and Part B data about patients who have had a visit with a primary care physician participating in the ACO during the performance year available upon request to participating ACOs. We suggest additional clarification regarding the timeline and how often this data will be provided to the ACO (suggest quarterly) and what time period will the data cover (suggest quarterly). We recommend this be synchronous with the Identification of Historically Assigned Beneficiaries, to include Name, HIC, race, and ethnicity.

AHIMA agrees with CMS that having an understanding of beneficiaries’ prescription drug information could be beneficial to ACOs for improving the care coordination of their patient population by avoiding duplication or adverse events. Regarding data related to substance abuse as it relates to Medicare Part D data, we recommend CMS provide clarification on this type of data and what, if any, Part D data will not be included. AHIMA proposes that the minimum data

elements be synchronous with Identification of Historically Assigned Beneficiaries; include Name, HIC, race, and ethnicity.

AHIMA recommends CMS send a monthly report of beneficiaries that have chosen the opt-out scenario to ACO so that the ACO does not continue to request identified data. This pertains to whether CMS expects to keep track of the beneficiaries' choice to "Opt-Out of Claims Data Sharing" functionality as discussed on page 76FR19559.

§ 425.9 Measures to assess the quality of care furnished by an ACO

AHIMA believes the measures chosen for the ACO are appropriate, however we do not agree that the measures should be given the same weight. We encourage CMS to consider the various patient populations and locations, as well as the issue of patient compliance. These are factors and variables that will impact the ACO performance. For example, information captured may be dependent on where a patient resides, they may have to wait much longer for an appointment if there are not an appropriate number of physicians per capita. These conditions may skew results for these ACOs, since they may fall very short in that measure, however, they may provide the best care possible.

We recommend CMS consider the National Quality Strategy's² priorities and goals and align with the domains discussed.

§ 425.10 Calculating the ACO quality performance score and determining shared savings eligibility

AHIMA supports the goals outlined under the "Use of Measures" section on page 76FR19569 in the proposed regulation. We strongly agree with CMS the measures should be aligned across Medicare and Medicaid's public reporting and payment systems, minimize administrative burden on providers to the extent possible, and measures should be nationally endorsed by a multi-stakeholder organization.

AHIMA supports and applauds CMS for its *"plan to continually align the ACO reporting requirements with those required for the EHR Incentive Program and leverage the infrastructure and measures specifications being developed for that program"* as stated on page 76FR19592. We believe this will assist in preventing and/or reducing administrative burden from potentially increasing. We also support CMS' goal to leverage the existing Group Practice Reporting Option (GPRO) tool that was developed for the Physician Quality Reporting System (PQRS) and building upon the system to support current and future ACO programs. We discourage the development of another reporting system that will increase administrative burden and recommend CMS limit the number of reporting tools required to comply with the program.

Implementing the ACO program will provide great opportunities in the sharing of data and better coordinated care for Medicare beneficiaries, however it will also create significant challenges for providers and hospitals as this is a relatively new care delivery model for many institutions. We have confidence as the program matures and the difficulties are resolved, experiences by patients and providers will continue to improve. We discourage the use of surveys as a source of data

submission for the program and recommend suspending the use of this process until the program has matured and consider this activity again in future rule making.

§ 425.11 Incorporating other reporting requirements related to the Physician Quality Reporting System and electronic health records technology

AHIMA is encouraged to see that CMS continues to make reference to its aspiration to align the Shared Savings Program and Meaningful Use program throughout the NPRM. However, we believe establishing the requirement as described on page 76FR19600 “*At least 50 percent of an ACO’s primary care physicians must be meaningful EHR users, using certified EHR technology as defined in § 495.4, in the HITECH Act and subsequent Medicare regulations by the start of the second performance year in order to continue participating in the Shared Savings Program*” to be extremely risky not only for the healthcare industry but for CMS as well. The two programs are significant in their undertaking and they have yet to be implemented and proven, therefore we strongly encourage CMS to remove the requirement of binding the two programs and reconsider this proposal when they have achieved a mature state. Additionally, Stage 2 of the Meaningful Use program is still undetermined and has an expected implementation year of 2013. With so many unknown details of both programs, AHIMA urges CMS to act prudently and untie the requirements.

AHIMA believes the number of required measures as shown on page 76FR19571 is considerably large and the industry is uncertain what the payment model will be; we encourage CMS to reduce the number of measures required for reporting. There is also the initiative during the time of the ACO program implementation to migrate to ICD-10-CM/PCS whereby the healthcare industry will be vigorously engaged. Quality measures will be undergoing significant changes and they will impact the numerator and denominator that is collected and reported.

§ 425.16 Audits and record retention

AHIMA recommends CMS provide additional clarity and guidance regarding the scope of audits that will be conducted. Specifically, we suggest providing information regarding whether the audit includes anyone who has provided a service to patient i.e., a locum tenens, off site laboratory or pathology, etc.

¹ “2011 Alzheimer’s Disease Facts and Figures,” Alzheimer’s Association, accessed May 16, 2011, <http://alz.org>.

² “Report to Congress - National Strategy for Quality Improvement in Health Care,” US Department of Health and Human Services, accessed May 16, 2011, <http://www.healthcare.gov/center/reports/nationalqualitystrategy032011.pdf>.