April 29, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St. SW, Floor 7
Washington, DC 20201

Via online submission at www.regulations.gov

RE: RIN 0955-AA01 – 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

I am pleased to submit the following comments on behalf of the Ambulatory Surgery Center Association (ASCA) in response to the Office of the National Coordinator for Health Information Technology (ONC) Proposed Rule implementing provisions of the 21st Century Cures Act. ASCA represents the interests of more than 5,700 Medicare-certified ambulatory surgical centers (ASCs) nationwide. ASCs are located in every state and offer a high-quality, convenient and low-cost choice for Medicare beneficiaries who do not require hospitalization after surgical or diagnostic procedures.

ASCA supports the interoperability goals outlined in the 21st Century Cures Act, as well as Section 1(c) of Executive Order 13813 which asserts the federal government's responsibility to improve patient's ability to make informed healthcare decisions. It is our belief that all stakeholders in the health care community owe patients the ability to access better, more useful information about the cost and quality of care available to them. However, we are concerned that certain provisions of the rule, if applied to ASCs, may be dangerously burdensome and reduce overall patient access to outpatient surgery. Therefore, ONC should include exemptions for ASCs until such time as health information technology (HIT) is standardized and widely available to centers, as well as continue ongoing work with ASCA to define ASC-specific certification requirements and clinical recommendations.

Health IT in ASCs

While ASCs represent a leading edge of outpatient surgical technique, EHR and HIT adoption lags behind many other facility types. Estimates from ASC EHR vendors put overall EHR penetration in ASCs at 15 to 20 percent, significantly lower than the 90 percent or greater penetration in hospitals and physician offices.

Some aspects of low penetration can be attributed to choice; ASCs tend to be small businesses that operate with a small staff and pragmatic budget. Many centers simply do not have the financial means or staffing capability necessary for procurement, implementation, and ongoing operation of a HIT system. Additionally, the core purpose of an ASC – to provide a single,

episode of care in less than 24 hours – does not require the ongoing, ancillary coordination often required for treatment in an office or hospital.

However, low penetration is undoubtedly also attributable to exclusion from the Meaningful Use (MU) program. ASCs were not eligible for stimulus payments under meaningful use, and the original MU objectives were specifically tailored to providers and hospitals. ONC's foundational 2011 Edition certification was designed to match MU requirements, and further stimulated the development of complete systems designed for use in either a physician office or hospital.

Past Exemptions

The lack of EHR (and HIT in general) proliferation has been noted both legislatively and regulatorily. Congress included Section 16003 in the 21st Century Cures Act, which states that no payment adjustment related to meaningful EHR use will be made for eligible professionals who furnish "substantially all" of their services in an ASC. The definition of "substantially all" was clarified in the CY 2018 Inpatient Prospective Payment System (IPPS) Final Rule; an ASC-based eligible professional is one who furnishes 75 percent or more of covered professional services in an ASC setting. Although the Meaningful Use program has changed considerably, this exemption continues via automatic reweighting of the Promoting Interoperability performance category in the Merit-Based Incentive Payment System (MIPS) for ASC-based clinicians. Pursuant to the 21st Century Cures Act, this exemption will last until three years after the Secretary of Health and Human Services determines that certified EHR technology "applicable to the ambulatory surgery center setting is available."

ASC Coverage and Possible Exemption from Information Blocking Proposed Rule

ONC proposes to use the definition of "provider" as found in Section 3000(3) of the Public Health Service Act (PHSA). This definition explicitly includes ambulatory surgical centers. Using a broad definition makes sense, as the Section 3022 of the 21st Century Cures Act does not constrain information blocking to only include providers using certain types of HIT (i.e. certified systems). Certainly, the goal of the interoperability as outlined in Cures Section 4003 is to include "all electronically accessible health information" not just that contained in certified systems.

However, Section 3022(a)(7) of the Cures Act issues a clarification to the formulation of information blocking disincentives by asserting that providers should not be penalized "for the failure of developers of health information technology…to ensure that such technology meets the requirements to be certified under this title." Given ASCs limited adoption of EHRs and other forms of HIT, as well as the aforementioned Section 16003 of the Cures Act which provides an exemption from negative MU payment adjustments, it seems clear that ASCs would be broadly covered by this clarification. Both Congress and HHS have a stated belief, codified via statute and rulemaking, that health information technology is not readily available for ASCs. While ASCA appreciates ONC's desire to capture all possible scenarios involving information blocking, the definition of provider as stated, without exemption for small provider types that may have little or limited access to HIT, creates a vague, overly-broad regulatory structure.

While supporting the intent of the proposal, ASCA urges ONC to include an exemption for ASCs and other provider types that do not have access to certified EHRs and the EHI contained within.

Request for Comments Regarding Including Price Information in EHI Definition (pg. 345)

ASCA appreciates the opportunity to comment on the proposal to include price information within the definition of electronic health information (EHI). ASCA and the ASC industry is firmly committed to price transparency. There can be no doubt that complex and disparate pricing practices have decreased the efficiency of the health care system and created a barrier for patients to access necessary care. However, including price information as part of the definition of EHI in this rule is beyond the intended scope of Section 3022 of the 21st Century Cures Act.

The proposed definition already encompasses individualized information related to "payment for the provision of health care." While agreeing that easing patient ability to shop for and understand the price of future care is important, codifying pricing information within the definition of EHI in this rule is not the correct framework for accomplishing that goal. Not only would it vastly increase the scope of possible information blocking activities, and therefore penalties, covered under this rule, but would set the foundation for ONC governance of pricing availability and technical standards without proper stakeholder input.

It is also possible that some actions contemplated in this RFI, such as a requirement that providers publicly post negotiated payer rates, would directly violate existing provider/payer contracts. The uneven implementation of the CMS's hospital price transparency requirement in the CY 2019 IPPS Final Rule is evidence that the issue of price transparency can be difficult and confusing even with focused regulation.

For these reasons, ASCA opposes including price information in the definition of EHI for this proposed rulemaking cycle.

Request for Information – Appropriate Disincentives for Providers

ASCA appreciates the opportunity to comment on appropriate disincentives for providers that are found to have committed information blocking.

Any new penalty that may be formulated or proposed for providers as the result of this RFI must undergo a separate rulemaking process. The providers subject to these disincentives range widely, and any system proposed by ONC or HHS would have to be carefully constructed so as not to disincentivize providers from practicing all together. For example, a penalty deemed reasonable for a hospital may be fatal for an ASC or other small facility type, thus lowering the overall availability of care for patients. The process of setting a penalty structure should be public and include as much feedback as possible from a range of provider types, so that any eventual penalty proposed by the Secretary per Section 3022(b)(2)(B) of the PHSA will be appropriate and not ultimately damaging to overall provision and availability of care.

Advocating for an ASC-Specific EHR Certification

In July 2017 ASCA staff began holding a regular call for ASC stakeholders to discuss EHR-related issues. Call participants include vendors offering HIT products for ASCs, facility staff, physicians, management company representatives and more; call agenda items typically include regulatory and legislative updates, general industry news discussion, and announcements of EHR education opportunities. From this group, ASCA formed a smaller workgroup of volunteers who would work towards developing a specific set of certification criteria most applicable for the ASC setting. Group participation was limited to one representative per vendor to encourage product-agnostic discussion.

The workgroup began by looking at the current 2015 Edition Criteria. Workgroup members were asked to independently provide responses as to whether they believed each criterion was applicable to ASCs. Reponses were compiled and the group discussed their experiences regarding certain criteria in the ASC setting. Criteria were eventually separated out into three groups: mandatory inclusion, optional inclusion, and criteria that would be included but needed to be re-written for ASCs.

In November 2017 ASCA staff and a workgroup representative met with ONC leadership to discuss obstacles to EHR development and uptake in ASCs. Subsequent meetings throughout 2018 led to the formation of a discrete team of ONC staff, primarily from the Office of Policy, to work with ASCA on developing ASC-specific EHR recommendations. A draft work plan with project goals and timelines was created but never finalized. Beginning in early 2019, ASCA staff began collaborating with specialty physician groups to garner feedback on opportunities for EHRs to improve clinical processes in ASCs.

We ask that ONC finalize the aforementioned ASC project work plan, and continue to work with ASCA's EHR Stakeholder Group to develop ASC-specific EHR certification requirements that will better contribute to the underlying goals of this rule and the 21st Century Cures Act.

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ASCA appreciates ONC acknowledging that all settings of care and practices of all sizes are necessary in order to provide higher quality and more efficient care, and the Agency's willingness to listen to our concerns as we strive to help our members the ability to continue providing provide high-quality patient care. We look forward to continuing to work with you and your staff. If you have any questions, please contact Kara Newbury at knewbury@ascassociation.org or 703.636.0705.

Sincerely,

William Prentice
Chief Executive Officer