

June 3, 2019

Secretary Alex M. Azar II  
Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule  
Mary E. Switzer Building  
Mail Stop: 7033A  
330 C Street SW  
Washington, DC 20201

RE: RIN 0955-AA01 - 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; published at Vol. 84, No. 42 Federal Register 7424-7610 on March 4, 2019.

*Submitted electronically via <http://www.regulations.gov>*

Dear Secretary Azar,

UnityPoint Health (“UPH”) appreciates the opportunity to provide comment on this proposed rule related to interoperability. UPH is one of the nation’s most integrated healthcare systems. Through more than 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Pioneer ACO Model. UnityPoint Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

UPH appreciates the time and effort of HHS, and particularly the Office of the National Coordinator (ONC), in developing this proposed rule and respectfully offers the following comments.

## DEREGULATORY ACTIONS

*This proposal identifies six items to reduce administrative burden: (1) Removal of a threshold requirement related to randomized surveillance which allows ONC-Authorized Certification Bodies (ONC-ACBs) more flexibility to identify the right approach for surveillance actions, (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR), (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Program, (4) removal of certain 2015 Edition certification criteria, (5) removal of certain Program requirements, and (6) recognition of relevant Food and Drug Administration certification processes with a request for comment on the potential development of new processes for the Program.*

***Comment:*** UPH always appreciate efforts to reduce administrative burden and is generally supportive. That said, ***ONC proposes to remove the problem list, medication list and medication allergy list from the 2015 Edition certification criteria. We disagree with the removal of these three criteria.*** While these criteria may be removed for the purpose of certification, it should be noted that these lists contain crucial clinical information which meet the definition of electronic health information. As a result, this change simply removes their standardization but not their use or presence within an electronic medical record.

## UPDATES TO THE 2015 EDITION CERTIFICATION CRITERIA

*This proposal would adopt revised and new 2015 Edition Criteria that incorporate: The United States Core Data for Interoperability Standard (USCDI); an electronic prescribing standard and certification criterion; clinical quality measures – report criterion; electronic health information (EHI) export; standardized API for patient and population services criterion; privacy and security transparency attestations; and data segmentation for privacy and consent management criteria.*

***Comment:*** ***Given the number of proposed changes, we are concerned with the aggressive 2-year timeframe for implementation.*** As a provider, we presently have a backlog of changes to our developers and vendors. Some of these are in response to other federal and state requirements, while others are being requested to improve workflows, efficiencies and satisfaction. The changes contemplated in this rule include fairly simple as well as complex coding. It is highly questionable that our vendors will be able develop, test, train and go live for all changes within 2 years. This concern is multiplied by providers nationwide. In addition, we fear that an overly aggressive and tight timeframe will only increase the price tag for providing these technology solutions. We do not believe that ONC adequately adjusted its cost estimates to reflect demand for these changes and taking into effect the cumulative demand for software changes from the other CMS fee schedules and quality initiatives.

## MODIFICATIONS TO THE ONC HEALTH IT CERTIFICATION PROGRAM

*This proposal would establish new and revised principles of proper conduct (PoPC) for ONC-Authorized Certification Bodies (ONC-ACBs). This includes clarification that records retention provision includes the “life of the edition” plus an additional 3 years after the retirement of an edition related to the certification of Complete EHRs and Health IT Modules.*

***Comment:*** As proposed, “life of the edition” begins with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations. For clarity surrounding these timeframes, ***we would request that ONC provide a separate posting or notice that lists the dates specific***

*when “life of the edition” starts and dates specific when “life of the edition” ends (i.e. a minimum of 3 years from the effective date that removes the applicable edition).*

## **INFORMATION BLOCKING**

*This proposal starts with a series of definitions and its impact on health care providers, health IT developers of certified health IT, networks, and exchanges. Electronic health information is inclusive of price information and comment is sought on the parameters and implications of including price information within the scope of EHI for purposes of information blocking.*

*In addition, this proposal identifies seven exceptions to the Cures Act information blocking definition. These exceptions are: (1) Preventing harm; (2) Promoting the privacy of EHI; (3) Promoting the security of EHI; (4) Recovering costs reasonably incurred; (5) Responding to request that are infeasible; (6) Licensing of interoperability elements on reasonable and non-discriminatory terms; and (7) Maintaining and improving health IT performance. This proposal also contains two additional Request For Information (RFI) - additional information blocking exception for complying with common agreement for trusted exchange, and scope of, and process for, disincentives for health care providers determined to have committed information blocking.*

### **Comment:**

- **Vague Penalty Structure:** First, while ONC is very explicit within this information blocking provision, its penalty structure is virtual silent. Under the Cures Act, information blocking carries a potential fine of up to \$1 million per violation. This proposed rule does not indicate how ONC will determine when violations will result in a fine and the penalty amount. Instead ONC has requested further information from stakeholders related to the scope of and process for disincentives for health care providers to information block. ***Without notice of the specific penalty structure and the potential for a \$1 million fine per violation, it is difficult to offer input on information blocking penalties at this time.*** We eagerly await future rulemaking on this topic.
- **Inclusion of Price Information:** In section 171.102, “electronic health information” includes “past, present, or future payment for the provision of health care to an individual.” In the preamble, ONC opines that payment information “may include price information.” ***While UPH supports price transparency, we have concerns with including price information as EHI, which is subject to information blocking and has the potential for significant fines.*** Our concerns appear justified by ONC’s list of 13 price transparency unknowns (i.e. technical, operational, legal, cultural, environmental and other challenges) for which stakeholder input is sought.<sup>1</sup> As we have stated in prior comment letters<sup>2</sup>, we do not believe that health care providers are the best source of pricing

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<sup>1</sup> See page 7514

<sup>2</sup> “Solicitation for Stakeholder Input related to a bipartisan effort to increase health care price and information transparency dated March 1, 2018” to Senators Cassidy, Bennet, Grassley, Carper, Young, and McCaskill accessed at <https://www.unitypoint.org/filesimages/GovernmentAffairs/PriceTransparency2018.pdf>; “CMS-1694-P – Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates” accessed at <https://www.unitypoint.org/filesimages/GovernmentAffairs/IPPS2018.pdf>; “CMS-1695-P – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs” accessed at <https://www.unitypoint.org/filesimages/GovernmentAffairs/OPPS2018.pdf>;

information for many consumers. Pricing information should be meaningful to consumers and enable consumers to make informed health care decisions in conjunction with other factors such as quality, experience and other patient satisfiers. ***Out-of-pocket costs are the costs that are most meaningful to consumers***, as it is the amount for which they are responsible. Out-of-pocket costs are most readily available from a consumer's insurer or health plan and may be obtained by contacting the health plan directly. As opposed to a health care provider, the third-party insurer will have access to the consumer's contract rates and specific benefits, such as deductibles, co-pays or co-insurances. The insurer also has the ability to give the consumer the full out-of-pocket costs that would include the hospital, physician and any other normal services for the episode of care. Insurers currently provide cost/liability information in a pre-authorization process as well as in an explanation of benefits document.

In contrast, CMS requires hospitals to make available a list of their current standard charges via the internet in a machine-readable format. Although hospital standard charges is a relatively easy price point to post, we do not believe it provides meaningful information for consumers. ***Hospital standard charges data is limited in that it reflects only inpatient and outpatient stays and procedures and is based on historical charges***. A key omission is the physician component, which adds costs especially when services or procedures involve multiple physicians. Aside from the posting of charges, our health system provides estimated pricing information to consumers for scheduled procedures and also has a phone line to provide price estimates for consumers who are planning or shopping for a service. It should be noted that while we strive to provide accurate and timely information, health care procedures and services are unlike a merchandise purchase in that complications may occur which may alter the original estimates.

***Other concerns about pricing data requiring clarification relate to the proposed use of negotiated rates, patient privacy and value-based arrangements***. ONC inquires about the inclusion of negotiated rates. If hospitals were mandated to post all negotiated rates, we can foresee that insurers will use them for anticompetitive reasons. In terms of patient privacy, we can envision situations in which the format of pricing information may be construed as information blocking. For instance, there are situations when a patient has a covered procedure but then elects an additional self-pay procedure during the same stay. Some costs during the procedure are not easily divided (infeasible). In addition, the patient often does not want to the insurer to know about the elective procedure (privacy of EHI). We are concerned that these well-intended exceptions may overlap, will require every health care provider to create new information blocking policies and procedures, and also entail significant documentation to justify use of the exceptions in the absence of such policies. Lastly, UPH has been an early adopter of Medicare valued-based arrangements – portions of our health system have participated in the Pioneer ACO Model, Medicare Shared Savings Program, Next Generation ACO Model, Bundled Payment Care Initiative, Medicare Care Choices Model, and Home Health Value-Based Purchasing Model. ONC acknowledges challenges with price transparency related to payment reform initiatives and seeks comment. We believe that these challenges themselves underscore the importance of insurers as the nexus for pricing information.

- Reasonable Standard within Exceptions: Information blocking exceptions are characterized as “reasonable” and necessary activities. Although the exceptions use “reasonable” in multiple instances to modify “belief,” “steps,” “time period,” and “alternatives,” we believe that verbiage is potentially unclear and litigious when used in the context of “cost.” We would suggest that ONC revisit these vague standards in favor of a more finite term or alternatively provide an example(s) to illustrate an “unreasonable” cost term.
  - Section 171.205 (“*Exception—Responding to requests that are infeasible*”) - The regulatory text permitting the recovery of costs references “costs” only; however, the preamble discussion makes clear that the amount charged may include a “reasonable” profit and still fit within the exception. ONC states that “complying with the requirements of this exception would not prevent an entity from making a profit in connection with the provision of access, exchange, or use of EHI. Indeed, the costs recoverable under this proposed exception could include a reasonable profit, provided that all applicable conditions were met.” Undoubtedly, the threshold for what profit margin is “reasonable” is very subjective.
  - Section 171.206 (“*Exception—Licensing of interoperability elements on reasonable and non-discriminatory terms*”) - ONC proposed another fee-based exception that would protect “reasonable” royalty fees associated with licensing and use of interoperability elements. Again, this standard raises questions regarding whether common license agreement terms are reasonable and non-discriminatory. For example, limitations of liability and indemnification provisions allocating risk for data security breaches are often contentious and subject to varying views of commercial reasonableness, particularly in contexts where compensation is cost-based.

We are pleased to provide input on this proposed rule and its impact on our integrated health system and the individuals and communities we serve. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at [sabra.rosener@unitypoint.org](mailto:sabra.rosener@unitypoint.org) or 515-205-1206.

Sincerely,

  
Laura Smith  
Chief Information Officer

  
Sabra Rosener  
VP, Government & External Affairs