Recommended Modifications to ONC's Proposed Rule

- The scope of the restriction on fees constituting prohibited blocking should be limited to requests by patients and those involved in patients' health care decisions – not all designees.
- If the scope of blocking prohibitions is limited to data contained in the USCDI, fees for general requests for medical records (which may contain some of the same content as the USCDI, but generally go beyond the USCDI) in non-USCDI format should be governed by state law.
- Release of information service providers should not be included within the definition of "Health Information Networks."
- A transition period of at least 36 months should be included in order to allow sufficient time for implementation.

Comments on ONC's Proposed Rule
21st Century Cures Act

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Summary

- The Proposed Rule does not reflect the substantial effort that provision of comprehensive electronic health record information (EHR) to patients and their designees requires
- The automated system that the Proposed Rule envisions is insufficient to deal with the underlying complexities of EHR retrieval and compilation
- ONC underestimates the substantial costs that will be required to achieve true interoperability
- ONC's proposal to require that electronic access to EHR be free is based on inaccurate information and a misapplication of economic principles
- The benefits that ONC enumerates are misspecified and do not take account of offsetting factors
- If the Proposed Rule is finalized without significant changes, ROI service providers will be unable to continue to fulfill requests for health records, resulting in inefficiencies and potential compromise of patient care

The Efforts Involved in Compiling EHR are Substantial

- Hospitals operate multiple systems to store EHR
  - On average, hospitals have 16 EHR systems
  - Only 2 percent of hospitals operate a single system
- These multiple systems are not integrated, requiring substantial effort to consolidate records
  - The codes used to identify patients may vary across systems
- HIPAA-protected sensitive personal health information, *e.g.,* diagnoses and treatment related to AIDS, behavioral health or substance use disorder, must be segregated and protected
- Some EHR requests require retrieving data from archived or paper systems
  - Providers required to exercise due diligence to locate all responsive information
  - Paper records now commonly stored offsite, typically with third-party vendors
  - Page by page review required once retrieved

ONC's Automated Approach to Patient EHR Access is Incomplete

- ONC's proposed approach is premised on health care providers already operating integrated systems to store their EHR
- ONC seemingly envisions APIs that transmit already-assembled, standardized information to the patient or patient-designee
- But, requests for EHRs are complex and may include
    - Clinical notes
    - Lab results
    - Images
    - Records transferred from other institutions
    - Archived and paper records

ONC's Cost Estimates are Implausibly Low when Compared to Historic Expenditures

- ONC estimates total one-time costs to automate access to data to facilitate interoperability range from $304 to $773 million, yet EHR implementation expenditures to date (which have not resulted in interoperability) have been many magnitudes greater
  - Federal Promoting Interoperability (Meaningful Use) payments totaled nearly $40 billion as of October 2018
  - The VA has contracted with Cerner for $16 billion to implement an EHR and achieve interoperability across its system
  - EHR implementations at single hospital systems have exceeded $1 billion
- Ongoing annual operating/updating costs estimated to range from $59 to $147 million, and average about $100 million
  - Current annual expenditures to comply with EHR requests are estimated to be at least $1.3 billion
    - This estimate is based on an estimate of total pages that are transmitted and a per-page cost

Providing Electronic Access to EHR for Free is Implausible

- ONC proposes that firms would not be permitted to charge patients or their designees for EHR that is provided electronically
- This proposal is impractical for two reasons
  - It is premised on an inaccurate perception that the incremental cost of providing EHR electronically is zero
  - Even if the incremental costs *were* zero, health care providers and their ROI service providers need to recover their fixed costs
    - ROI service providers will be unwilling to provide services at a loss or to invest in new technology or services
- Health care providers will be forced to pass on the costs they incur to patients and payors indirectly
  - Only about 5 percent of total requests that Ciox processes originate with patients
  - If providers are unable to charge other "customers" to cover their fixed and variable costs, patients and insurers will bear those costs

ONC Overstates the Likely Benefits of its Proposed Rule

- ONC posits at least three benefits from increased interoperability
  - Reduced provider burden
  - Cost-saving reduced utilization of health care services
  - Greater patient access to medical records
- These benefits are likely overstated
  - Provider burden stems from excessive data entry requirements of EHRs not from a lack of interoperability
  - Estimates of cost reduction from reduced utilization are based on multiple speculative assumptions
  - Only a very small minority of patients with access to their records electronically actually use them
- ONC does not consider at least two offsetting factors that could increase health care expenditures
  - Increased health care provider revenue capture due to improved coding
  - Increase in defensive medicine due to increased malpractice litigation