AMCP | Academy of Managed Care Pharmacy®

June 3, 2019

Donald Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW, Room 7033A
Washington, DC 20201

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

Dear Dr. Rucker:

The Academy of Managed Care Pharmacy (AMCP) thanks the Office of the National Coordinator for Health Information Technology (ONC) for the opportunity to provide comments in response to its proposed rule "*21st Century Cures Act: Interoperability, Information Blocking, and the Health IT Certification Program*" published in the Federal Register on March 4, 2019. AMCP appreciates ONC's effort to remove barriers to interoperability and health information exchange. We look forward to continued dialog with ONC on how managed care pharmacy can be integrated into topics that seek to achieve full interoperability in the health care system.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP supports ONC's implementation of the 21st Century Cures Act (Public Law 114 -255) as it relates to expanded use of health information technology (health IT) and information exchange. As a member of the Pharmacy Health IT Collaborative[1] AMCP also supports its comment submission. AMCP has also leveraged our members' expertise to offer the additional recommendations that follow.

Section IV. Updates to the 2015 Edition Certification Criteria

[1] Pharmacy Health Information Technology Collaborative. Available at: https://www.pharmacyhit.org/. Accessed on May 24, 2019.

§170.205(b) Electronic Prescribing

AMCP supports ONC's proposal to update the electronic prescribing (e-Rx) SCRIPT standard in 45 CFR 170.205(b) to NCPDP SCRIPT standard, Implementation Guide Version 2017071, which would result in a new e-Rx standard eventually becoming the baseline for certification. This standard was approved in 2017 to provide for communication of prescription or prescription related information between prescribers and dispensers for the older named transactions and a handful of new transactions listed at §423.160(b)(2)(iv). Version 2017071 also contains electronic prior authorization (ePA) transactions, as well as transactions for new prescription requests, transfers, and Risk Evaluation and Mitigation Strategy (REMS) requests and responses.[2] ONC's proposal to update the e-Rx SCRIPT standard to the Implementation Guide Version 2017071 is also aligned with a final rule recently issued by the Centers for Medicare & Medicaid Services.[3]

Section VI. Health IT for the Care Continuum

Health IT and Opioid Use Disorder Prevention and Treatment – Request for Information

ONC is seeking information on health IT functionalities and standards to support the effective prevention and treatment of opioid use disorders (OUD) across patient populations and care settings. AMCP is committed to resolving issues associated with the opioid epidemic and established an Addiction Treatment Advisory Group (ATAG) in 2016 to evaluate current gaps and barriers to addiction treatment services and develop initial recommendations to improve access to addiction treatment.[4] [5] The AMCP Addiction Advisory Group (AAG), established in March 2018, continues AMCP's ongoing efforts to promote best practices that improve addiction prevention and treatment services. The AAG has compiled numerous resources on the AMCP website that may be useful to ONC on opioid use disorder prevention and treatment.[6] AMCP encourages ONC to utilize us as a resource on this topic.

---

[2] National Council for Prescription Drug Programs. NCPDP SCRIPT Version 2017071 ePrescribing Testing Tool Now Available. September 13, 2018. Available at: http://www.ncpdp.org/NCPDP/media/pdf/pressrelease/SCRIPTv-2017071Testing-Tool-Now-Available-091318.pdf. Accessed May 24, 2019.

[3] Centers for Medicare & Medicaid Services. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. 82 Federal Register 100. May 23, 2019. Codified at 42 CFR Parts 422, 423.

[4] The Role of Managed Care Pharmacy in Improving Access to Naloxone: A Viewpoint Article and Findings from the Addiction Treatment Advisory Group. Journal of Managed Care & Specialty Pharmacy. December 2016. Available at: http://www.jmcp.org/pbassets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf. Accessed on May 24, 2019.

[5] Findings and Considerations for the Evidence-Based Use of Medications Used in the Treatment of Substance Use Disorder: A Viewpoint Article and Findings from the Addiction Treatment Advisory Group. Journal of Managed Care & Specialty Pharmacy. December 2016. Available at: http://www.jmcp.org/pbassets/Outserts/The%20Role%20of%20Managed%20Care%20Pharmacy%20%20-%20Dec%202016.pdf. Accessed on May 24, 2019.

[6] AMCP. Addiction Advisory Group. Available at: http://www.amcp.org/aag/. Accessed on May 29, 2019.

To fully assess the risk potential for a patient, it is important for payers and managed care professionals to understand the full opioid use profile for a patient, including opioids that are administered in a physician's office, emergency department, or other health care setting. Tools such as PDMPs are mechanisms that identify patients at risk for harm and help coordinate patient care and improve outcomes. AMCP supports interoperability of PDMPs that are integrated into EHRs and dispensing systems. We encourage ONC to help facilitate the sharing of best practices around user-centered design so that clinicians, including pharmacists and managed care professionals, encounter common interface and workflow design elements as they transition between different care settings as well as EHR technologies.

Section VIII. Information Blocking

Applicability

ONC is proposing that information blocking would apply to health care providers, health IT developers of certified health IT, health information exchanges, and health information networks, as those terms are defined in section §170.102. We note that in this section of the proposal, health care provider has the same meaning as "health care providers" defined in the Public Health Service Act at §3000(3) of 42 U.S.C. 300jj. As often as is possible, we request that ONC explicitly state organizations intended by the term "health care providers". In our experience, health plans and managed care organizations are subject to information blocking by relevant actors who misinterpret the term to apply only to individuals and entities providing direct patient care. A level of specificity should be used to clarify to who the term "health care provider" refers to.

Please also see the reference from ONC's authorizing legislation:

> "LII U.S. Code Title 42. THE PUBLIC HEALTH AND WELFARE
> Chapter 6A. PUBLIC HEALTH SERVICE Subchapter XXVIII.
> HEALTH INFORMATION TECHNOLOGY AND QUALITY
> Section 300jj. Definitions
>
> *(3)Health care provider*
>
> *The term "health care provider" includes a hospital, skilled nursing facility, nursing facility, home health entity or other long-term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, bloodcenter, ambulatory surgical center described in*

section 1395l(i) of this title,[1] emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title,[1] a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary."

Request for Comment Regarding Price Information

ONC is seeking comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care. AMCP believes that furthering prescription drug price transparency is critical to lowering overall drug costs, and patients' out-of-pocket costs. One solution that we generally support is the use of real-time benefit check (RTBC) that would allow beneficiary-specific out-of-pocket cost information to be viewed at the point of prescribing. However, we encourage ONC to work with the National Council for Prescription Drug Programs (NCPDP) to adopt a balloted and recognized standard for real time benefit checking (RTBC) for industry to follow. Adoption of a non-standardized RTBC solution may result in end-users being presented with information that varies in quality and accuracy. The burden to health plans, pharmacy benefit managers, and managed care organizations will be greatly reduced if they are able to implement using one standard approach.

Moreover, CMS recently finalized a rule that would require use of real-time benefit tools (RTBTs) in the Part D program by January 1, 2021,[7] but is strongly encouraging Part D plans to start implementing a RTBT prior to this date. AMCP encourages ONC to coordinate with CMS and include certification requirements and testing for a RTBT in the health IT certification programs. The burden for meeting certification requirements for a RTBT should lie with the technology vendors, not the PDP sponsors who rely on vendors to provide usable functionality.

Section VIII. D Proposed Exceptions to the Information Blocking Provisions

[7] Centers for Medicare & Medicaid Services. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. 82 Federal Register 100. May 23, 2019. Codified at 42 CFR Parts 422, 423.

ONC proposes seven "reasonable and necessary activities" that do not constitute information blocking and would be excepted from any penalties. In general, AMCP wants to ensure that information sharing can happen for managed care pharmacy entities and patients. As such, we provide feedback to ONC on the following proposed exceptions:

Preventing Harm

AMCP does not support organizational policies that would broadly restrict the secure exchange of information for approved purposes. AMCP supports ONC's proposed review on a case by case basis in accordance with organizational policies for safety and avoidance of harm.

Promoting the Privacy of Electronic Health Information

Due to 42 CFR Part 2's strict requirements, providers and health plans have long struggled over the use and disclosure of substance use disorder treatment records as part of coordinated care efforts. As such, AMCP encourages ONC to work with OCR to clarify where HIPAA is harmonized with Part 2 requirements on the confidentiality of certain substance use disorder patient records for the purpose of treatment, payment, and health care operations.

The current barriers to accessing a patient's entire medical record, including addiction records, lead to potentially dangerous medical situations such as harmful drug-drug interactions and lack of patient-centric, integrated care. As the country moves forward with combating the opioid epidemic, a focus should remain on integrating substance use disorder, mental health, and primary care services to improve patient outcomes and support care coordination.

AMCP continues to support the need for codification of these provisions into the HIPAA statute, but in the meantime, providers, patients and payers require clear guidance in this area. Lack of clarity around the application of HIPAA and Part 2 places a significant burden on clinicians to interpret compliance with existing regulations. If clinicians could better understand these regulations, they could better coordinate care and minimize a substantial source of burden.

Recovering Costs Reasonably Incurred

In line with the Administration's goal for price transparency, the fees and costs of information exchange should be made publicly available. This is one way to ensure that costs that the actor incurred due to Health IT being designed or implemented in non-standard ways do not unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using electronic health information. AMCP seeks clarification on whether fees and costs of

information exchange will be publicly posted and encourages the ability to publicly share and compare this information across entities.

Additionally, AMCP seeks clarification on the term "reasonable" as this term may be interpreted differently across entities. Furthermore, requests could have varying rates if they are pulled by the batch, for an individual, or even for different time frames.

Conclusion

AMCP appreciates your consideration of the recommendations and concerns outlined above and looks forward to continuing work on these issues with ONC. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer