NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 16, 2025

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Thomas Keane., M.D.
Assistant Secretary for Technology and Planning and
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW
Washington, DC 20201

Submitted via www.regulations.gov

Re: Request for Information; Health Technology Ecosystem; CMS-0042-NC

Dear Dr. Oz and Dr. Keane:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the request for information issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of the Assistant Secretary for Technology and Planning (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively ASTP/ONC) regarding strategies to build a more modern, resilient, and patient-centered health technology ecosystem.

NACDS endorses the objectives set forth by CMS and ASTP/ONC to cultivate a health ecosystem that puts patients at the forefront. It is critical that this initiative diminish barriers to health data access and exchange to improve care and yield better health outcomes. Furthermore, we agree that although HHS has instituted a policy framework to facilitate the seamless and secure flow of health information among patients, providers, and payers, there remains considerable potential to refine and streamline our healthcare ecosystem. One essential, and overdue improvement is the meaningful inclusion of pharmacies in the nation's healthcare data infrastructure.

The importance of including pharmacies in interoperability initiatives was recently highlighted by ASTP/ONC's establishment of the Health Information Technology Advisory Committee (HITAC) Pharmacy Interoperability and Emerging Therapeutics Task Force and its charge to advance pharmacy interoperability to support medication management, patient safety, and consumer engagement. We share this commitment to better connecting healthcare providers, patients, caregivers, and stakeholders to strengthen health information exchange. The Task Force's regular meetings in 2023 culminating in its November 2023 recommendations represent important steps toward that goal.[1]

With respect to the Task Force's recommendations, NACDS reinforces our request that ASTP/ONC prioritize those with the greatest potential impact—particularly focusing on: (1) bi-directional data sharing between pharmacies and other providers; (2) integrating pharmacists into care teams; and (3) collaborating with HHS to incentivize development and adoption of certified Health IT, including through full recognition of pharmacists as providers. Prioritizing these three areas would deliver meaningful progress toward pharmacy interoperability, and NACDS looks forward to continued collaboration with ASTP/ONC and others to implement these recommendations.

[1] https://www.healthit.gov/sites/default/files/page/2023-11/2023-11-09_PhIET_TF_2023_Recommendations_Transmittal_Letter_508.pdf

For context, pharmacists were deemed ineligible for the CMS Electronic Health Record (EHR) Incentive Program (now known as the Medicare Promoting Interoperability Program), because pharmacists are not classified as healthcare providers under the Social Security Act, despite being the most accessible healthcare providers in the country. Current legislation introduced in the House, H.R.3164 - Ensuring Community Access to Pharmacist Services Act, would help rectify this oversight. Numerous Medicaid programs and private/commercial health plans across the country already recognize pharmacists as healthcare providers, although Medicare lags behind because of this statutory constraint. However, CMS and ASTP/ONC have the authority to include pharmacies in interoperability initiatives irrespective of this legislation.

NACDS also recommends that CMS and ASTP/ONC explore methods to promote and incentivize the use of certified health IT beyond the CMS incentive programs, as these incentives apply to only a subset of HIT users, significantly limiting their effectiveness. Support, education, and incentives should be provided to all participants in the health data exchange ecosystem, including pharmacies and entities involved in electronic health information (EHI) exchange on their behalf, to encourage the adoption of standardized and certified health IT.

For an efficient and patient-focused digital health ecosystem, it is necessary to pass a comprehensive federal law that protects consumer health information not covered by HIPAA. This law should incorporate key elements of the HIPAA framework, which have been effective, and align with HIPAA in its approach, concepts, and definitions. This federal law and HIPAA should clearly preempt state laws concerning health data privacy, rather than just establishing a federal baseline as HIPAA currently does. This necessity for comprehensive federal preemption has become increasingly critical as numerous states have enacted extensive data protection laws due to the lack of progress at the federal level. This has resulted in a complex web of varying data protection regulations. This complexity poses challenges and confusion for patients and consumers, while also imposing significant burdens and costs on businesses, without delivering corresponding privacy benefits. Additionally, it hampers technological advancements and innovation, particularly in the field of artificial intelligence (AI), as disparate regulations governing data usage for AI development and deployment exist across different states, creating operational and compliance obstacles.

Additional feedback on specific questions included in the RFI is outlined below.

Data Accessibility and Interoperability (PR-3)

NACDS fully supports ASTP/ONC's initiatives to improve interoperability, facilitate public health reporting and exchange, and maintain consistent and robust health information technology (HIT) standards. NACDS advocates for policies that enable pharmacists to conveniently access patient-specific clinical information, such as lab data, vitals, medications, diagnoses, and hospitalization data to provide personalized care. This access supports better health outcomes and cost-effective care, in addition to promoting patient safety, closure of care gaps, medication adherence, enhances clinical trial screening, and helps measure key outcomes.

Ensuring that all data within an EHR system is accessible for exchange, irrespective of storage format, is essential for healthcare delivery. Every format must be accessible and readable, as this allows healthcare providers to make well-informed decisions, promote efficiencies, and formulate personalized and effective treatment plans. EHR interoperability plays a significant role in enhancing workflows, reducing ambiguities and redundancies, and enabling seamless data transfer among EHR systems and healthcare stakeholders, including providers and patients.

TEFCA (PR-6)

It is crucial that TEFCA participants and those exchanging EHI can trust that TEFCA requirements are enforced correctly, and that there is prompt action against entities that violate these requirements. Without this assurance, the TEFCA standards may not effectively promote interoperability. NACDS requests that ASTP/ONC consider measures to safeguard TEFCA participants from entities that misrepresent their intentions for seeking EHI.

As more organizations see value in participating in TEFCA, ASTP/ONC and the Recognized Coordinating Entity (RCE) should consider ways in which they can facilitate and encourage their transition to TEFCA. This could involve education, incentives, and other forms of engagement, such as through the provision of technical and financial assistance to providers.

Specifically, ASTP/ONC could enhance TEFCA participation by expanding the TEFCA Manner Exception that was implemented on January 1, 2025. This exception specifies that if both parties (requestor and responder) participate in TEFCA, it is not considered information blocking to fulfill requests for EHI solely through TEFCA. However, this may inadvertently discourage a requestor from becoming a TEFCA participant, as the exception does not apply to a non-participating requestor. Instead, ASTP/ONC could motivate entities to join TEFCA by adjusting the exception to require any requester who is not currently a TEFCA QHIN participant, or sub-participant to justify why joining TEFCA is infeasible or poses an undue burden. This adjustment would align with the goals of the exception and promote adoption within the industry.

It is crucial that the process for adopting TEFCA requirements be transparent, comprehensible, and inclusive of stakeholder input. Given that certain practices associated with TEFCA requirements, which involve withholding or restricting EHI, do not constitute information blocking, it is vital that these requirements undergo thorough vetting. To achieve this, TEFCA requirements should be codified in regulation. All significant issues and core concepts, including foundational definitions of different exchange purposes, should be incorporated into regulation following the notice and comment rulemaking process, rather than being addressed in TEFCA documents such as SOPs, which lack the rigorous review process of regulations.

This approach is essential to ensure that TEFCA requirements are well-vetted and reflect a broad range of stakeholder feedback while also fostering trust and confidence among TEFCA entities, actors, and their interactions. Achieving widespread adoption and national interoperability hinges on the healthcare sector's understanding, trust, and ability to provide input on the TEFCA framework. Accordingly, we recommend that any privacy and security requirements for TEFCA participants align with HIPAA unless there are compelling policy reasons to implement different standards.

Information Blocking (PR-12, PR-13)

Fostering interoperability helps support care coordination and better and safer health care. NACDS supports ASTP/ONC's intent with respect to information blocking rules to the extent that it would achieve these aims, as we agree that actors' knowingly engaging in information blocking would inhibit progress toward robust interoperability. However, NACDS opposes information blocking policies that focus almost exclusively on the punishment of healthcare providers. We believe that ASTP/ONC should first consider policies that emphasize education, technical assistance, and incentives before imposing penalties on healthcare providers. Since information blocking policies are relatively new, there likely will be healthcare providers who are not completely educated on their provisions and

requirements. Education and technical assistance, therefore, would better achieve ASTP/ONC's goals, as opposed to after-the-fact penalties imposed on the unaware that may run counterproductive to ASTP/ONC's goals. Education and technical assistance would likely lead to fewer instances of information blocking and a greater sharing of electronic health information.

Beyond NACDS' concerns related to a penalty-focused approach to preventing information blocking in general, specifically, we also are extremely concerned by the fact that pharmacies and pharmacists, unlike most other healthcare providers, are subject to penalties without the commensurate incentives that most other healthcare providers enjoy through the certification program. As ASTP/ONC is aware, pharmacies and pharmacists are not eligible for incentive payments for the adoption of health information technology. Consequently, ASTP/ONC's information blocking rules impose a much heavier burden on pharmacies and pharmacists relative to most other health care providers. This is because other healthcare providers would be subject to a disincentive in the form of a less robust incentive, whereas pharmacies and pharmacists would actually *not receive a disincentive*. They would, in fact, *receive a punishment much worse*—in the form of a financial or other similar penalty, that may even reduce capacity and ability to invest in interoperability.

Should ASTP/ONC reject our recommendations and maintain a penalty-focused approach, then we urge ASTP/ONC, at the very least, not to impose penalties in the first instance against health care providers, such as pharmacies and pharmacists, that are not eligible for incentive payments. It is for these providers in particular where ASTP/ONC should prioritize education and technical assistance. These providers have not had the benefit of over a decade of incentive payments, as most other health care providers have had, to help ensure they are fully versed in ONC's health information technology policies. In fact, many of these health care providers have had no or minimal interaction with ASTP/ONC. Surely, their first interaction with ASTP/ONC should not be the agency pursuing them to impose penalties.

In addition to ensuring that pharmacies are not inappropriately penalized under information blocking rules, CMS should work with ONC to ensure that pharmacists are not excluded from EHR vendor application programming interface (API)access, are not subject to unreasonable fees for access to patient clinical data, and are treated equitably under the information blocking rules. Pharmacists must be able to access the clinical data they need to effectively treat patients.

As ASTP/ONC identifies emerging practices that aim to circumvent the information blocking regulation or diminish its effectiveness, it is recommended to address these issues through additional guidance and enforcement actions whenever feasible. This approach will maintain the flexibility of the regulation, permit broader applicability, and prevent it from becoming overly intricate and detailed.

We also suggest that ASTP/ONC review the Protecting Care Access exception and the Individual Request not to Share EHI sub-exception under the Privacy Exception. The threshold condition for the Protecting Care Access exception, specifically the good faith belief that the person is "at risk of potentially being exposed" to legal action, may be too low, particularly when EHI is requested for treatment purposes. For example, the mere disclosure of EHI related to certain medications could meet this standard, which might allow actors to withhold such EHI without information blocking repercussions.

To balance patients' and providers' fears with the need for EHI in healthcare, a higher threshold could be set, requiring an objective basis for using EHI for legal actions against either party. Alternatively, ASTP/ONC might limit

exceptions to cases where disclosure is prohibited under HIPAA rules. This ensures consistency with the HIPAA Privacy Rule and equal treatment of HIPAA and non-HIPAA entities.

NACDS has similar concerns regarding the Individual Request not to Share EHI sub-exception within the Privacy exception. As with the Protecting Care Access exception, we are apprehensive about the potential unintended consequences of extending protection under the information blocking rule to actions taken by an actor that contravenes another law. We believe a more effective balance between patient privacy concerns and public welfare would be achieved by reinstating the limitation that permits the use of this sub-exception unless disclosure is mandated by law. Aligning the exception with HIPAA reduces complexity, and the broader exception may negatively impact patient care if an actor opts to withhold EHI based on this exception.

USCDI (TD-7)

NACDS endorses USCDI as it establishes a standardized set of health data classes and elements necessary for nationwide, interoperable electronic health information exchange, which pharmacists require. ASTP/ONC's USCDI integrates with FHIR US Core, although not all elements of USCDI are mapped, and the names of USCDI Data Classes and Elements may differ from those of FHIR US Core resources and elements. We are pleased that progress is being made to better align USCDI and FHIR US Core.

Digital Health Adoption & Essential Data in Value-Based Care (VB-3, VB-4)

NACDS has long supported the transition to value-based care as a cornerstone of CMS' strategy to incentivize improvements in health outcomes rather than increases in service volume, and we underscore the essential role of technology in achieving success in value-based care. NACDS continues to advocate for broader integration of pharmacies into value-based care models across Medicare, Medicaid, and commercial plans, as a myriad of evidence supports the effectiveness of pharmacists in improving health outcomes and reducing preventable costs, including in rural and other vulnerable populations. Pharmacists as medication experts are positioned to help reverse increased spending attributable to suboptimal medication use and promote better health outcomes.

Importantly for Medicare beneficiaries, it was estimated that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of Medicare fee-for-service expenditures, millions in hospital days, and thousands of emergency department visits that could have been avoided. If the 25% of beneficiaries with hypertension who were nonadherent became adherent, Medicare could save $13.7 billion annually, with over 100,000 emergency department visits prevented and 7 million inpatient hospital days that could be averted.[2] While pharmacists can help curb these wasteful spending trends and improve health more broadly, they have been largely underutilized by payers, including Medicare and Medicaid. More detail on the tremendous value of including pharmacies in CMS' work to advance value-based care can be found in a 2021 report available here.

Based on a recent survey conducted by NACDS, 75% of NACDS members have participated in some type of value-based care arrangement with pay-for-performance models being the most common arrangements, followed by risk-based models, and then shared savings models. NACDS members have a range of experience in value-based care, including some with more than 10 years of experience. The most common clinical interventions part of value-based care models that NACDS members have participated in include medication adherence initiatives, gap closures, A1c and blood pressure measurement and improvement initiatives, and vaccinations, in alignment with CMS star ratings

[2] Lloyd, Jennifer T., Maresh, Sha, Powers, Christopher, Shrank, WH, Alley, Dawn E; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; Medical Care; January 2019.

measures, and HEDIS measures. The most common partners for pharmacies in value-based care arrangements are Medicare Advantage plans, followed by Medicaid plans, and a few pharmacies are partnering with commercial plans, however, pharmacies remain vastly underutilized in value-based care across payers.

Examples of Pharmacy Value

- A review by the Department of Veterans Affairs, including over 60 research studies, found that patients receiving chronic care management from a pharmacist had a higher likelihood of meeting blood pressure, cholesterol, and blood glucose goals, compared to those receiving usual care.[3][4]

- A retrospective study that assessed clinical outcomes in patients with diabetes, with and without management by a pharmacist, found that the pharmacy intervention group had greater improvements in the individual areas of A1c, blood pressure, and statin goal attainment. In this study, 40 percent of patients in the pharmacist intervention group achieved all three clinical goals after the intervention, compared with only 12 percent of patients in the usual care group.[5]

- In another study conducted in 12 community pharmacies in Asheville, N.C., two employers offered their employees with diabetes an identical pharmacy benefit described as an employer-sponsored wellness program focused on diabetes. Total mean direct medical costs decreased by $1,200 to $1,872 per patient per year compared with baseline. Days of sick time decreased every year for one employer group, with estimated increases in productivity estimated at $18,000 annually.[6]

- Also, a large midwestern health system participating in the Pioneer ACO program used pharmacists to focus on the highest-risk members. Pharmacists saw over 670 ACO patients, resolving over 2,780 medication-related problems and contributed to improved care in complex patients with diabetes. The percentage of diabetes patients optimally managed was significantly higher for patients who received care from pharmacists (21% vs. 45%, $P < 0.01$). The program also showed a 12:1 return on investment (ROI).[7]

What are essential health IT capabilities for value-based care arrangements? (VB-3a)

For pharmacies, the most essential health IT capabilities for value-based care arrangements are data extraction/normalization, quality performance measurement, attribution and patient ID matching, and patient event notification. In particular, standardized quality performance measurements that are agreed upon across participating stakeholders are important. Other important capabilities are access to claims data, remote device interoperability, mechanisms for pharmacies to document the clinical interventions performed and outcomes achieved, and datasets that are automatically reportable (rather than manual reporting).

[3] Carmichael, J. et al. (2016). "Healthcare metrics: Where do pharmacists add value?" *Am J Health-Syst Pharm*. 73: 1537-47.
[4] Greer N, Bolduc J, Geurkink E et al. (2016). "Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care." *Ann Intern Med*.
[5] Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. (2018). "The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home." *JMCP*. 24(5):423-429.
[6] Carole W. Cranor, Barry A. Bunting, Dale B. Christensen, The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program, Journal of the American Pharmaceutical Association (1996), Volume 43, Issue 2, 2003.
[7] Brummel A, et al. Best practices: improving patient outcomes and costs in an ACO through comprehensive medication therapy management. J Manag Care Spec Pharm. 2014 Dec;20(12):1152-8.

Ideally, all capabilities would be available and updated in real-time. Unfortunately, pharmacies generally do not have the ability to access information nor input information into patients' medical records, which makes value-based care participation challenging. It is important that pharmacies have medical record access to both view relevant information, document pharmacists' interventions, and communicate with patients' other care providers, including for recommendations and medication-related approvals, as needed. Aside from clinical data, it is also important that pharmacies have access to information from health plans, including eligibility information and patient referral opportunities.

What other health IT capabilities have proven valuable to succeeding in value-based care arrangements? (VB-3b)

Pharmacies have achieved success in data sharing for value-based agreements with the partner with a third-party vendor who can support data transfer, data analysis, display the data, or serve as an intermediary for data, and separately, leverage SFTP (Secure File Transfer Protocol) sites, however barriers persist as outlined below. Some pharmacies have invested in integrated systems that interface with the pharmacy dispensing software or pharmacy management system to improve efficiencies and use for pharmacy staff.

What are the essential data types needed for successful participation in value-based care arrangements? (VB-4)

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, multi-stakeholder forum for developing and promoting industry standards and business solutions that improve patient safety and health outcomes, while also decreasing costs. The work of the organization is accomplished through its members who bring high-level expertise and diverse perspectives to the forum. NCPDP's consensus process provides a model for creating health information technology (HIT) solutions essential to new reform efforts. In recent years, NCPDP has undertaken efforts to identify the essential data elements for pharmacies participating in value-based care arrangements. NACDS urges CMS to coordinate with NCPDP and other pharmacy stakeholders to better integrate pharmacies into the healthcare technology ecosystem.

The specific, essential data elements depend on the outcome desired or the intervention being performed, however, generally pharmacies need: demographic information to identify and match patients paired with eligibility information, clinical values, such as labs, A1c, blood pressure, the most recent medication list and fill history, and other relevant clinical interventions performed. Ideally, pharmacies would have full access to patient records, including the ability to access information from and input information into medical records.

Interoperability Challenges (VB-11)

While pharmacies are making progress toward more interoperable systems, pharmacies generally do not have efficient mechanisms for data sharing across the healthcare ecosystem as a result of limited incentives and cost-prohibitive technologies. Therefore, pharmacies must often build unique processes for each value-based arrangement they participate in, primarily driven by preferences of each payer. This makes operationalizing value-based initiatives particularly challenging and burdensome for pharmacies.

What specific interoperability challenges have you encountered in implementing value-based care programs? VB-11

Some of the top barriers pharmacies face include lack of real-time data sharing, inconsistent data formats, definitions, platforms, structure and quality across partners, reliance on third-party vendors for data exchange,

difficulty integrating electronic medical records and pharmacy systems, and limited visibility into patient records and lab values. While pharmacies have found success in partnering with third party vendors to support data transfer and display, barriers include lack of real time data transfer, and cost-prohibitive requirements. Also, in partnering with third party vendors to support data sharing with health plans, the data that supports the final outcomes is not always available, and reporting is segmented, which makes proving outcomes challenging. Pharmacies must expend significant resources toward translating nonstandard data files, manual data reporting, supporting and managing the data, analytics, and different definitions, systems, processes, and definitions across health plans intensifies the burden and complexity for pharmacies.

Conclusion

NACDS strongly supports the vision for a connected, secure, and effective health technology ecosystem. To realize this vision, it is crucial to fully acknowledge and integrate the role of pharmacies. We respectfully encourage CMS and ONC/ASTP to adopt an approach that includes pharmacies in upcoming activities concerning interoperability, data modernization, and digital infrastructure. Thank you for considering our comments. For follow up, please contact NACDS' Dr. Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at sroszak@nacds.org or 703-837-4251.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.