NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 15, 2026

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Submitted via http://www.regulations.gov

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS–0062–P)

Dear Administrator Oz:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule on interoperability standards and prior authorization for drugs (CMS-0062-P).

NACDS supports CMS' overall goal to expand electronic prior authorization, advance application programming interface (API)-enabled data exchange, and reduce administrative burden. However, to achieve meaningful improvements in patient access and provider efficiency, the final rule must ensure that interoperability requirements are operationalized in the context of real-world workflows, including within pharmacy systems and dispensing environments where coverage and prior authorization barriers are most acutely encountered.

The policies finalized through this rulemaking will shape how coverage information, prior authorization requirements, and clinical documentation are exchanged across payers, providers, and pharmacies. Accordingly, CMS should prioritize implementation approaches that deliver actionable, real-time information; and ensure consistent, enforceable execution across payers. Absent these refinements, there is a risk that expanded data exchange will increase system complexity without reducing burden or improving patient access.

NACDS Recommendations

I. Pharmacy Integration Must Be Core to Interoperability Policy

- CMS should require that interoperability infrastructure, including APIs, prior authorization processes, and data exchange mechanisms, be usable within pharmacy dispensing and clinical documentation systems and support pharmacists in both roles.

II. Interoperability Standards Must Align with Pharmacy Workflows

- CMS should maintain NCPDP SCRIPT as the foundational standard for electronic prior authorization across pharmacy benefit programs to ensure consistency and reduce administrative burden.
- CMS should retract its proposal to require impacted payers to support the PANotification transaction within the NCPDP SCRIPT standard.
- NACDS strongly recommends that CMS maintain requirements for both the NCPDP Formulary and Benefit (F&B) and Real Time Prescription Benefit (RTPB) standards, and clarify their complementary roles in supporting end-to-end visibility, from formulary design and utilization management policies to patient-specific coverage determination, across prescribing and dispensing workflows.

III. Prior Authorization Must Be Real-Time, Actionable, and Workflow-Integrated

- CMS should require prior authorization and real-time benefit information to be actionable, with clear next steps, defined submission pathways, visibility into required documentation, and bidirectional data exchange to reduce delays and manual burden at the point of dispensing.

IV. CMS Must Address Fragmentation Between Pharmacy and Medical Benefit Drugs

- CMS should preserve distinct pharmacy and medical benefit standards while addressing fragmentation by enabling clear, real-time determination of coverage pathways and supporting user workflows that reduce confusion for pharmacists and other providers.

V. Transparency Must Be Actionable at the Point of Care

- CMS should require prior authorization denial reasons to be standardized, structured, and actionable within real-time workflows, enabling pharmacists to immediately determine next steps, reducing manual follow-up, workflow disruption, and delays in patient access.

VI. Implementation Must Reflect Operational Reality

- CMS should account for variability in payer and pharmacy infrastructure, particularly delegated pharmacy benefit functions and uneven health IT maturity, by enabling flexible, phased implementation that works across real-world pharmacy workflows and avoids shifting burden or delaying patient access.
- CMS should clearly define prior authorization timeframe triggers, including when a request is received, deemed complete, and how iterative submissions are handled, to ensure accountability is appropriately assigned and not shifted to downstream stakeholders.
- NACDS strongly recommends a minimum 24-month implementation timeline from the effective date of the final rule to ensure readiness and effective implementation of required changes across pharmacy and payer systems.

VII. Support Transition to FHIR-Based Standards

- NACDS supports FHIR adoption but urges a phased, flexible transition aligned with existing NCPDP standards and pharmacy workflows to avoid duplicative systems and ensure seamless interoperability without disrupting patient access.

VIII. Reponses to CMS' Requests for Information (RFI)

- CMS should include pharmacies as eligible participants in electronic event notifications to support care transitions, medication management, and improved patient outcomes.
- CMS should prioritize healthcare system resiliency and continuity at the point of dispensing by requiring reliable, redundant APIs and fallback processes that enable pharmacies to maintain patient access during system disruptions.

- CMS should strengthen payer API requirements by ensuring consistent, standards-based implementation, transparent endpoint discovery, and enforceable compliance, so APIs function seamlessly across payer, provider, and pharmacy systems rather than creating new inefficiencies.
- CMS should leverage interoperability to make step therapy portable, data-driven, and patient-centered, enabling recognition of prior therapy history across payers and reducing delays and disruptions in care continuity.
- CMS should reduce delays and administrative burden by standardizing and extending electronic prior authorization workflows for laboratory and DMEPOS services, ensuring better coordination and integration with pharmacy-supported care.

Discussion

I. Pharmacy Integration Must Be Core to Interoperability Policy

CMS' interoperability framework appropriately emphasizes APIs, standards adoption, and data exchange. However, the proposed rule continues to reflect a system architecture that is primarily oriented around payers and prescribers, without fully operationalizing the role of pharmacies.

Pharmacists routinely identify coverage barriers, facilitate access to medications, and deliver an expanding set of clinical healthcare services. Importantly, pharmacists operate in a dual role within today's healthcare system, both as dispensers dependent on external clinical documentation and as rendering providers responsible for generating and submitting documentation for clinical services. Interoperability policies that fail to reflect this dual role will perpetuate gaps in workflow design and reduce the effectiveness of prior authorization reforms.

CMS should require that interoperability infrastructure, including APIs, prior authorization processes, and data exchange mechanisms, be usable within pharmacy dispensing and clinical documentation systems and support pharmacists in both roles.

II. Interoperability Standards Must Align with Pharmacy Workflows

A. Maintain NCPDP Standards as the Foundation of Pharmacy Interoperability for Medication Dispensing Workflow

CMS appropriately proposes adoption of the NCPDP SCRIPT, Formulary & Benefit (F&B), and Real-Time Prescription Benefit (RTPB) standards as the foundation for pharmacy benefit transactions. NACDS strongly supports this approach and emphasizes that these standards are built for medications and related supplies covered under the pharmacy benefit.

CMS should maintain NCPDP SCRIPT as the foundational standard for electronic prior authorization across pharmacy benefit programs to ensure consistency and reduce administrative burden.

B. Remove PANotification Requirement for Payers

CMS proposes requiring impacted payers to support the PANotification transaction within the NCPDP SCRIPT standard. NACDS recommends that CMS remove this requirement.

The PANotification transaction is designed to support communication between prescribers and pharmacists to reduce duplicate prior authorization submissions and improve coordination at the point of dispensing; it does not involve payers.

Requiring payer participation would introduce unnecessary complexity into a pharmacy-centered workflow, creating confusion regarding transaction roles and potentially disrupting real-time coordination between prescribers and pharmacies. For pharmacists, this could increase duplicate prior authorization activity and drive additional manual intervention, ultimately delaying patient access to needed therapies.

CMS should maintain clear alignment between transaction design and real-world workflow roles to ensure that PANotification continues to support efficient, pharmacy-integrated prior authorization processes.

C. Maintain Both Formulary & Benefit (F&B) and Real-Time Prescription Benefit (RTPB) Standards

CMS proposes requiring impacted payers to support both the NCPDP F&B and RTPB standards and seeks comment on whether maintaining both standards provides value or introduces unnecessary burden. NACDS strongly recommends that CMS maintain requirements for both the NCPDP F&B and RTPB standards, as they serve distinct and complementary functions.

The F&B standard provides plan-level formulary and utilization management information that is broadly used across the prescribing ecosystem to understand coverage structure, including whether prior authorization, step therapy, or other requirements may apply. This information is typically available earlier in the workflow and helps inform initial prescribing decisions.

RTPB, by contrast, provides patient-specific benefit information at the point of prescribing or dispensing, including real-time confirmation of coverage, cost-sharing, and whether prior authorization is actually required for the individual patient under their current benefit design. Importantly, these capabilities are not interchangeable. F&B does not provide patient-specific confirmation, and RTPB cannot function without the more detailed, transaction-specific inputs (e.g., pharmacy, quantity, days' supply) that occur later in the workflow.

Eliminating or de-emphasizing either standard would shift burden downstream to pharmacies, increasing the likelihood of rejected claims at the point of dispensing, triggering manual prior authorization processes, and delaying patient access to therapy.

CMS should maintain both F&B and RTPB requirements and clarify their complementary roles in supporting end-to-end visibility, from formulary design and utilization management policies to patient-specific coverage determination, across prescribing and dispensing workflows.

III. Prior Authorization Must Be Real-Time, Actionable, and Workflow-Integrated

NACDS agrees that CMS' proposals to expand electronic prior authorization are directionally correct. However, success will depend not simply on the availability of data, but on whether that information can be used effectively within real-world clinical and dispensing workflows.

Today, pharmacists and other providers often receive coverage and prior authorization information that indicates requirements but does not clearly support next steps. In practice, this requires additional interpretation, manual follow-up, and repeated submissions, contributing to workflow inefficiencies and delays in patient access to therapy.

For pharmacists, these gaps are most acute at the point of dispensing, where coverage determinations, prior authorization requirements, and patient access converge. When information is not actionable, pharmacy staff must rely on phone calls, resubmissions, and coordination with prescribers to move forward, introducing avoidable delays in therapy initiation.

CMS should ensure that prior authorization and real-time benefit responses are actionable within both clinical and medication dispensing workflows. At a minimum, responses should:

- clearly indicate whether prior authorization is required,
- identify the appropriate submission pathway (e.g., pharmacy vs. medical benefit),
- specify required documentation or additional information needed to proceed, and
- support efficient initiation of prior authorization with prescribers within existing system capabilities.

CMS should also ensure that pharmacists can meaningfully participate in prior authorization workflows where appropriate. Pharmacists are frequently the first to identify prior authorization requirements and are well positioned to facilitate coordination with prescribers and payers. Enabling seamless pharmacist participation can reduce delays and improve workflow efficiency, particularly in time-sensitive dispensing scenarios.

In addition, CMS should support bidirectional data exchange capabilities that allow pharmacists, providers, and payers to exchange documentation and respond to requests within integrated systems. While not all workflows can be fully automated at this time, improving the ability to exchange information across actors can reduce reliance on manual processes and duplicative submissions.

Finally, CMS should ensure that real-time benefit and prior authorization information is accessible within pharmacy systems, rather than limited to prescriber-facing environments. Without this access, pharmacists remain dependent on fragmented processes that delay patient access and increase administrative burden.

CMS should also consider the patient-facing implications of its API proposals, particularly because the agency seeks input on consumer-facing capabilities related to prior authorization. Expanding access to prior authorization status and related information will be most effective if that information is not only available, but understandable and usable within the context of medication access workflows. Patient-facing tools should help individuals understand the status of a prior authorization request, what steps may be needed next and who is responsible for those steps, and when follow-up with the prescriber, plan, or pharmacy may be appropriate. Without this context, greater data availability may improve visibility without meaningfully improving the patient experience.

Absent these improvements, there is risk that the proposed policies will improve data availability without fully addressing workflow inefficiencies, shifting administrative burden rather than reducing it and continuing to delay patient access to care.

IV. CMS Must Address Fragmentation Between Pharmacy and Medical Benefit Drugs

CMS seeks comment on distinguishing drugs covered under pharmacy versus medical benefits. NACDS emphasizes that pharmacy-specific standards should not be repurposed for medical benefit workflows.

At the same time, the bifurcation of benefit administration could create real-world confusion. Pharmacists and other providers often lack a single, reliable method to determine coverage pathways and prior authorization

requirements. CMS should preserve appropriate standards alignment while advancing policies that reduce fragmentation, particularly by promoting clear routing and consistent signaling of benefit category.

V. Transparency Must Be Actionable at the Point of Care

NACDS strongly supports CMS' proposal to require specific reasons for prior authorization denials. This is a critical step toward improving transparency, reducing unnecessary rework, and enabling more efficient resolution of coverage barriers.

However, for pharmacists and other providers, transparency is only meaningful if it is operationalized within workflows. Today, denial information is often inconsistent and unstructured. As a result, pharmacy staff must contact prescribers or plans for clarification and reinitiate prior authorization requests, introducing avoidable delays in patient access to therapy.

At the point of dispensing, where pharmacists must make immediate determinations about how to proceed, lack of clear and usable denial information leads directly to workflow disruption. Prescriptions may be held, patients may be asked to return later, and staff must engage in manual outreach to determine next steps. These inefficiencies increase administrative burden and contribute to patient frustration and therapy abandonment.

CMS should ensure that denial information is not only provided but also is actionable within real-time pharmacy workflows. Specifically, CMS should ensure that payers align denial reasons with clear, actionable next steps, such as whether additional documentation is required, whether an appeal is appropriate, or whether alternative therapy should be considered.

Importantly, denial transparency should support workflow resolution, not simply provide retrospective explanation. Pharmacists should be able to use denial information to immediately determine how to proceed, whether by coordinating with the prescriber, initiating a revised submission, or advising the patient on next steps, without requiring additional clarification from the payer. CMS should also ensure that denial reason data is incorporated into broader interoperability efforts, including real-time benefit tools and prior authorization workflows, so that coverage requirements and resolution pathways are visible throughout the prescribing and dispensing process.

Absent these refinements, the requirement to provide denial reasons risks improving visibility without improving usability, leaving existing inefficiencies in place, and continuing to delay patient access to care.

VI. Implementation Must Reflect Operational Reality

A. Recognize Infrastructure and Workflow Variability

NACDS encourages CMS to recognize the variability in infrastructure, system capabilities, and operational models across impacted stakeholders. While the proposed rule appropriately advances standardized approaches to interoperability and prior authorization, successful implementation will depend on CMS' ability to account for the uneven maturity of underlying systems and workflows across the healthcare ecosystem.

In particular, pharmacy benefit functions, including prior authorization processing, real-time claims adjudication, and benefit determination, are often delegated across multiple entities, including pharmacy benefit managers, third-party administrators, and technology vendors. This distributed model introduces additional complexity in aligning systems, exchanging data, and ensuring consistent implementation across trading partners. Policies that

assume a centralized payer infrastructure risk creating misalignment between regulatory requirements and operational realities.

CMS should also recognize the uneven advancement of health IT infrastructure across care settings, including within pharmacy. While federal programs accelerated adoption of EHRs and interoperability capabilities among many traditional provider settings, pharmacies were largely excluded from those incentives. As a result, pharmacists are increasingly participating in clinical, documentation-driven workflows, including prior authorization, without the same level of system support, integration, or data exchange capability available in other care settings.

This mismatch has direct implications for implementation. Pharmacists frequently must act on coverage and prior authorization requirements in real time at the point of dispensing, yet often must rely on fragmented systems, manual communication channels, and multiple intermediaries to complete those tasks. Without accounting for these constraints, new interoperability requirements may introduce additional complexity rather than streamline workflows.

CMS should explicitly account for variability in infrastructure and operational models by:

- allowing flexibility in implementation pathways, particularly where functions are delegated across various entities,
- supporting phased or staged adoption that reflects differences in system readiness,
- ensuring that interoperability requirements are designed to function across diverse settings, including pharmacy management or dispensing systems that may not mirror EHR-based environments, and
- avoiding assumptions of uniform system capability or centralized control across payers and trading partners.

Recognizing these differences is critical to ensuring that policy changes translate into workable solutions at the point of care. Without this flexibility, the risk is that stakeholders will implement technically compliant solutions that do not function effectively in practice, leaving pharmacists to bridge gaps through manual processes and delaying patient access to care.

B. Clarify Prior Authorization Timeframes ("PA Clock")

CMS should provide greater clarity on prior authorization timeframes, including:

- when a request is considered received,
- when it is considered complete, and
- how iterative submissions and requests for additional information are treated.

Without clear definitions, accountability may shift to downstream actors lacking control over documentation completeness.

C. Establish Realistic Implementation Timelines

NACDS strongly recommends a minimum 24-month implementation timeline from the effective date of the final rule. Industry experience shows that even standard version transitions require at least this amount of time, and the

proposals in this rule introduce new functionality for many entities. A longer implementation period would also avoid requiring compliance with NCPDP SCRIPT version 2017071 during a transition window, given the scheduled move to version 2023011 on January 1, 2028.

VII. Support Transition to FHIR-Based Standards

NACDS supports CMS' adoption of FHIR-based standards as a critical step toward modernizing healthcare data exchange and enabling more interoperable, real-time workflows. However, the transition to FHIR-based approaches must be implemented in a manner that reflects the complexity of existing systems and the diversity of stakeholder capabilities.

Across the healthcare ecosystem, entities are at different stages of readiness for FHIR adoption. In pharmacy, in particular, system architectures are often designed around high-volume transaction processing rather than EHR-centric data exchange models. As a result, implementation of FHIR-based APIs must be carefully coordinated to avoid disrupting established workflows or creating parallel systems that increase, rather than reduce, complexity.

CMS should support a deliberate and flexible transition to FHIR-based standards by:

- establishing phased implementation timelines that allow stakeholders to build, test, and integrate new capabilities in a coordinated manner,
- providing flexibility for those with limited infrastructure capacity, including community pharmacies, and
- ensuring alignment between FHIR-based requirements and existing standards, including NCPDP transaction standards, to prevent duplication or inconsistencies.

Coordination with existing standards is particularly important. Pharmacy workflows currently rely on mature NCPDP standards, while CMS appropriately proposes use of FHIR-based workflows for prior authorization of drugs covered under the medical benefit.

The core challenge is not the use of distinct standards, but the lack of clear coordination between them. Without reliable, real-time signals that indicate which pathway applies, providers and pharmacists may face duplicative or conflicting processes. CMS should maintain standards integrity while prioritizing alignment and routing clarity.

CMS should also recognize that successful FHIR adoption depends not only on technical implementation, but on workflow integration across systems and actors. Standards should be deployed in a manner that supports seamless interaction between providers, pharmacies, and payers, rather than requiring users to navigate multiple uncoordinated platforms.

A carefully managed transition will allow CMS to realize the long-term benefits of FHIR while avoiding short-term disruption to patient access and care delivery.

VIII. Responses to CMS' Requests for Information (RFI)

NACDS strongly supports CMS' efforts to modernize prior authorization through interoperable, standards-based electronic processes. However, successful implementation requires full integration of community pharmacy into interoperability frameworks, enforceable payer compliance with standardized APIs, and policies that prioritize real-world workflow functionality and patient access. NACDS recommends actions across electronic event notifications,

API implementation, step therapy, resiliency, and prior authorization processes to ensure these reforms translate into measurable improvements in care delivery and administrative efficiency.

A. Electronic Event Notifications for Value-Based Care and Care Coordination

NACDS supports CMS' exploration of electronic event notifications as a tool to improve care coordination and patient outcomes. However, to be effective, these notifications must include community pharmacies as eligible participants in the care continuum.

Pharmacies are uniquely positioned to support patients during care transitions, particularly following hospital admissions or discharges, where medication changes, new prescriptions, and adherence risks are most acute. Without timely access to relevant patient event information, pharmacists are limited in their ability to perform medication reconciliation, identify therapy gaps, and support continuity of care.

CMS should ensure that pharmacies are included among the entities eligible to receive electronic event notifications. Including pharmacies in event notification frameworks will strengthen care coordination and improve medication management outcomes, and other clinical outcomes, particularly for patients with chronic and complex conditions.

B. Increasing Healthcare Resiliency

NACDS recognizes the importance of strengthening healthcare system resiliency in the face of growing cybersecurity threats and infrastructure vulnerabilities. Pharmacies operate in real-time environments that are highly dependent on payer connectivity and interoperable systems.

Disruptions to payer systems, APIs, or data exchange infrastructure, whether due to cyber incidents or technical failures, have immediate consequences for patient access to medications.

CMS should prioritize resiliency requirements that ensure continuity of care at the point of dispensing by:

- establishing expectations for API reliability and redundancy across impacted payers,
- supporting fallback mechanisms and contingency pathways that allow pharmacists to proceed with dispensing when systems are unavailable, and
- coordinating implementation timelines and requirements to minimize operational disruption for pharmacy systems and technology vendors.

Resiliency policies should recognize pharmacies as critical access points in the healthcare system and ensure that infrastructure failures do not result in delays in therapy or patient harm.

C. Improving Implementation of Payer Application Programming Interface (API) Technology

NACDS supports CMS' focus on improving the implementation and oversight of payer APIs. However, consistent and effective interoperability depends not only on technical standards, but on how those standards are implemented and validated in real-world workflows.

Variability in API implementation across payers creates significant challenges for pharmacies, which must interact with multiple payer systems in real time. Without consistent implementation and testing, APIs risk introducing new inefficiencies rather than reducing administrative burden.

CMS should strengthen implementation and oversight of payer APIs by:

- requiring consistent, standards-based implementation across payers to avoid proprietary or non-standard approaches,
- supporting real-world testing and validation, including testing with pharmacy systems and dispensing workflows,
- establishing a centralized, transparent mechanism for API endpoint discovery to reduce administrative burden associated with locating payer systems, and
- developing clear compliance and accountability mechanisms, including audit and reporting processes to address non-conformance.

APIs should be evaluated based on their ability to function seamlessly across payer, provider, and pharmacy environments, not solely on technical conformance.

D. Step Therapy

NACDS appreciates CMS' interest in leveraging technology to improve step therapy processes. Current step therapy policies can create significant barriers to care, particularly when patients are required to repeat previously unsuccessful therapies after switching plans or coverage. Pharmacies play a key role in identifying these issues, as they frequently have visibility into a patient's medication history and treatment patterns.

CMS should prioritize solutions that make step therapy processes more patient-centered and interoperable by:

- supporting data exchange mechanisms that enable payers to access and recognize prior step therapy history,
- leveraging existing interoperability frameworks, including Payer-to-Payer APIs, to facilitate portability of medication and utilization management history, and
- encouraging standardization of step therapy documentation to reduce variability across payers.

Policies should ensure that prior therapy experiences are recognized across coverage transitions, reducing unnecessary delays in treatment and improving continuity of care.

E. Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items

NACDS shares CMS' concern regarding the impact of prior authorization requirements on access to laboratory services and DMEPOS items. Pharmacies increasingly provide or support services that intersect with these categories, including point-of-care testing and chronic disease management.

Delays and coordination challenges associated with prior authorization for laboratory tests and supplies can directly impact patient care and exacerbate administrative burden for pharmacies.

CMS should:

- promote standardization of prior authorization requirements across service types, including laboratory and DMEPOS categories and
- ensure that electronic prior authorization capabilities are extended consistently to these areas.

Reducing fragmentation and improving coordination in these areas will support more efficient care delivery and improve patient outcomes.

Conclusion

NACDS appreciates CMS' leadership in advancing interoperability and prior authorization reform and supports the rule's overall direction. To deliver meaningful improvement in patient access and administrative efficiency, however, the final rule must do more than expand data exchange requirements, it must ensure that those requirements work in real-world workflows, particularly in pharmacy settings where coverage, authorization, and patient care needs converge.

CMS should finalize policies that provide actionable, real-time information; preserve clear distinction between pharmacy and medical benefit standards; and support consistent and enforceable implementation across payers. CMS should also ensure that implementation timelines and compliance expectations reflect operational realities across the healthcare ecosystem, including the uneven infrastructure and system readiness that persist across stakeholder types.

With these refinements, CMS can establish a stronger and more durable framework, one that not only modernizes prior authorization, but also reduces fragmentation, improves care coordination, and better supports timely patient access to needed therapies.

NACDS appreciates the opportunity to comment and looks forward to continued engagement. For further discussion, please contact Kayla McFeely, Senior Vice President, Health & Wellness Strategy and Policy, at kmcfeely@nacds.org.

Sincerely,

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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.