Navigating the **New Norm** in a **Regulatory Storm**

Rules From CMS and ASTP/ONC Raise the Bar for E-Prescribing and Interoperability—Yielding Challenges and Opportunities for EHR and HIT Vendors

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Introduction

Imagine a vast ocean under a clear sky, with gentle waves promising calm and continuity for your product roadmap. But on the post-pandemic horizon, clouds begin to gather, signaling a significant shift.

Think of the regulatory lull as that clear sky and the new and proposed policies as a storm making landfall. The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), which recently changed its name to the Office of the Assistant Secretary for Technology Policy (ASTP), are making big moves.

For EHR and health IT vendors, these updates and new rules will present roadmap and development challenges along with significant opportunities to innovate and enhance product offerings. Final rules from CMS and ASTP/ONC, along with the latter's recently proposed HTI-2 rule, bring new e-prescribing and data portability requirements that will shape the future of healthcare technology.

To help you navigate choppy regulatory waters, this booklet covers key aspects of the CMS final rule—how it could impact product roadmaps, compliance efforts, and the enhancement of e-prescribing systems. It explores the ASTP/ONC's HTI-1 final rule and the HTI-2 proposed rule, exploring their impact on data interoperability, patient access, and health IT certification.

As with any storm, preparation is crucial. It also explains how to align your product roadmap with new regulations and proposed rules, allowing you to maintain compliance while streamlining effective medication management solutions for your customers.

Anticipating this and future regulatory shifts better positions your organization to weather policy changes and emerge stronger.

Part 1: The CMS Final Rules

CMS released final rules under CMS-4201-F3 and CMS-4205-F, mandating the adoption of new e-prescribing standards. These updates are designed to enhance the efficiency and effectiveness of electronic prescriptions, with significant implications for EHR and HIT vendors. There are three distinct standards.

1. Real-Time Prescription Benefit (RTPB) Standard Version 13 (NEW)

RTPB provides real-time information about patient-specific prescription benefits, including estimated out-of-pocket costs, in-network and out-of-network pharmacy coverage, and personalized prior authorization checks. This allows for more informed and cost-effective prescribing decisions at the point of care.

Key elements include:

Patient-specific benefits provide detailed benefit information, including estimated out-of-pocket costs for patients.

Pharmacy coverage that includes information for both in-network and out-of-network.

Personalized prior authorization checks to facilitate quicker and more efficient processing.

Generalized payer-specified alternatives to promote cost-effective prescribing.

Payer adoption that will lead to more frequent and meaningful cost conversations with patients.

Effective: January 1, 2027.

2. Formulary and Benefit (F&B) Version 60 (NEW)

The new National Council for Prescription Drug Programs (NCPDP) F&B version 60 outlines detailed information on a patient's prescription benefits at the plan level, facilitating more accurate and comprehensive medication management.

This is the first major change in almost 10 years. It includes general, plan-level prescription benefits relative to other medications within the patient's plan, specifying covered versus non-covered medications, plus:

Categorization and tiering to allow for a better understanding of coverage and cost implications.

Payer-specified alternatives to help prescribers consider cost-effective options.

Plan-level prior authorization to streamline the approval process.

Effective: January 1, 2027.

3. NCPDP SCRIPT Standard 2023011

This standard will replace version 2017071 as the core e-prescribing standard for transmitting prescriptions and prescription-related information, including medication history and electronic prior authorization (ePA) transactions, using electronic media for covered Part D drugs for eligible individuals.

Key features include:

Modernized patient identifiers to enhance accuracy and efficiency across systems, impacting intake, documentation, scheduling, interoperability, and admission, discharge, and transfer (ADT) workflows.

Revamped medication segments to improve patient safety. Structured and codified sigs (prescription instructions) are modified based on real-world use and will likely become required under ASTP/ONC's HTI-2.

New message types for ePA including notifications between pharmacies and prescribers to reduce duplication of efforts.

Other refinements: This version improves workflows for canceling prescriptions, receiving dispense notifications from pharmacies, and handling renewals. It also offers extensibility and other enhancements to better support evolving needs.

Effective: July 17, 2024.

The transition period, during which either version of the NCPDP SCRIPT standard may be used, will end on January 1, 2028, when the NCPDP SCRIPT standard version 2017071 expires for U.S. Department of Health and Human Services (HHS) use. Beginning January 1, 2028, entities must exclusively use NCPDP SCRIPT standard version 2023011 for Part D e-prescribing.

Implementation

The new standards introduced by CMS will take effect in phases, providing a structured approach for EHR and HIT vendors to develop, certify, and deploy the necessary updates. The new regulations are designed to enhance the e-prescribing process, improve workflow efficiencies, and contribute to better patient outcomes.

Why Did CMS Modify the Previous Proposal?

CMS modified the initial proposal to enhance the effectiveness and manageability of the new regulations for providers and EHR/HIT vendors alike. CMS made these changes to:

1. **Repackage priorities into multiple final rules:** CMS distributed its priorities across several final rules to ensure a more focused and organized implementation process. This approach allows stakeholders to better understand and adapt to specific changes without being overwhelmed by a single, extensive rule.

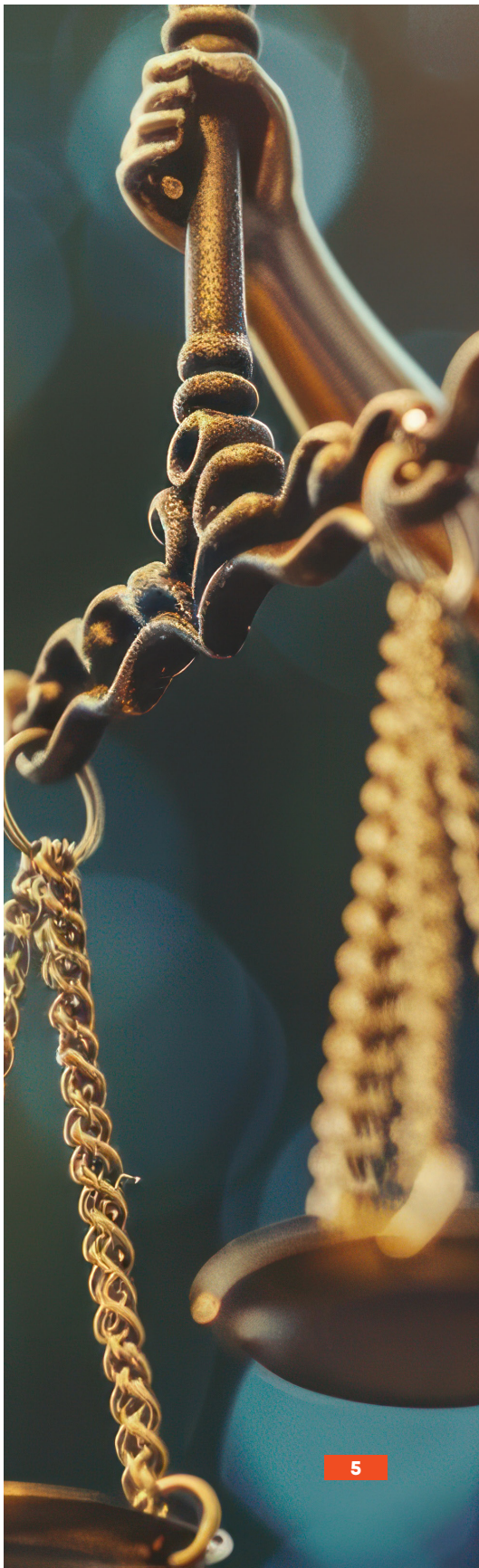
2. **Increase the scope of the original proposal:** By broadening the scope of the initial proposal, CMS aims to cover a wider array of issues and opportunities within the healthcare system. This expansion ensures that the regulations address more comprehensive aspects of healthcare delivery and technology.

3. **Propose a longer compliance deadline to support a phased rollout for providers:** CMS has extended the compliance deadlines, recognizing the complexity of the new requirements. This phased rollout gives providers and vendors more time to adjust, develop, and integrate necessary changes into their systems gradually—without unnecessary chaos or upheaval.

4. **Refine standards alignment:** To avoid conflicts and confusion, CMS has refined its standards to align more closely with those set by the ASTP/ONC. This harmonization ensures that all regulatory requirements are consistent and cohesive.

5. **Prevent the need for selective enforcement of misaligned rules:** By addressing potential misalignments between different rules, CMS aims to eliminate the need for selective enforcement. This ensures that all providers and vendors are held to the same standards, promoting fairness and uniformity in the healthcare industry.

6. **Accelerate improvements in formulary tools to support meaningful cost conversations with patients:** One of the primary goals of the updated regulations is to enhance formulary tools. These improvements empower providers to have more meaningful and informed cost discussions with their patients, ultimately supporting better decision-making and patient outcomes.



What's Interesting About This Final Rule?

The latest CMS final rule brings several noteworthy elements that mark a significant shift in the regulatory landscape for healthcare technology, says Nick Barger, PharmD, Vice President of Product at DrFirst, and author of the Regulatory Talk series in Healthcare IT Today.

Here's what stands out, according to Barger:

1. **The end of the "regulatory lull:"** After a period of relative calm, the regulatory environment is gearing up for substantial changes. This narrow window of opportunity exists to finalize the regulatory framework before the 2024 election in November. Vendors and providers need to act swiftly to align with these new requirements.

2. **Major impacts across medication management:** The final rule introduces a comprehensive uplift in e-prescribing, affecting the following facets of medication management:

   - Significant changes will be made in how prescriptions are written, formatted, and transmitted. This will enhance clarity and accuracy, reduce errors, and improve patient safety.
   - How medication history is received from pharmacies and payers will undergo substantial improvements, ensuring more accurate information flow.
   - The process of completing prior authorizations between providers and payers will be streamlined, reducing administrative burdens and accelerating patient care.

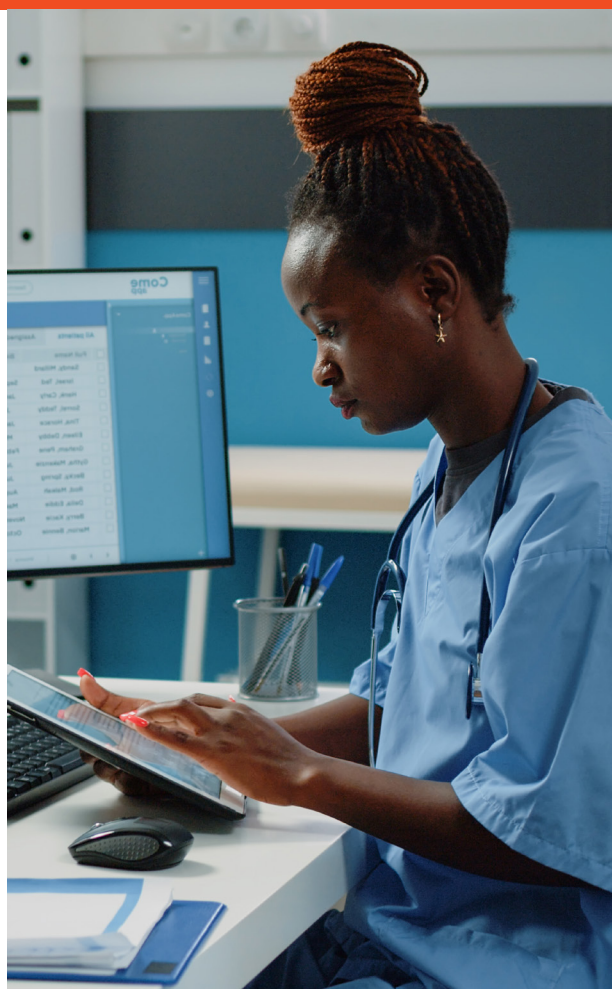
3. **RTPBs:** For the first time, the rule requires real-time prescription benefit standards. This innovation will allow providers to access real-time information on patient-specific prescription benefits, including estimated out-of-pocket costs and coverage details. This will enable more informed and cost-effective prescribing decisions at the point of care.

4. **New requirements—major version change for F&B:** This update, the first in almost a decade, modernizes patient identifiers and revamps medication segments. It includes enhancements like improved patient safety through updated structures and codes and new ePA message types.

5. **Simultaneous implementation with ASTP/ONC's HTI-2 rule:** The nw requirements will likely coincide with the implementation of the HTI-2 rule. This means vendors and providers must prepare for simultaneous compliance with both sets of regulations, emphasizing the need for comprehensive planning and execution.

The final rule represents a seminal moment for the healthcare industry, focusing on enhancing e-prescribing and medication management. By understanding and adapting to these changes, EHR and HIT vendors can ensure compliance while improving workflow efficiencies and patient outcomes.

Part 2: The ASTP/ONC's HTI-1 and HTI-2 Rules



The ASTP/ONC has played a pivotal role in advancing healthcare interoperability and e-prescribing standards through two critical regulations: the HTI-1 final rule and the recently proposed HTI-2 rule.

These rules create a more cohesive and robust regulatory environment, aligning closely with CMS regulations. While both share the overarching goal of enhancing the exchange of health information, they differ in their focus and scope.

HTI-1 laid the foundational framework for interoperability, establishing baseline standards, patient access, and data security. In contrast, HTI-2 builds on this foundation by introducing more advanced requirements, expanding the scope of interoperability, and pushing for significant upgrades in e-prescribing and real-time price transparency.

Here's a closer look at the key elements of the HTI-2 proposed rule:

Comprehensive Overhaul of E-Prescribing

The HTI-2 proposed rule demands a total upgrade of e-prescribing systems, building upon CMS standards. This includes the adoption of NCPDP SCRIPT Standard 2023011 to facilitate more accurate and efficient e-prescribing processes as well as ePA integration into the base EHR's workflows.

Streamlined Prior Authorizations

By mandating the use of standardized Application Programming Interfaces (APIs) for prior authorization, the rule aims to create a more efficient and faster data exchange process between health IT systems and payers. This will reduce delays and administrative burdens, ultimately improving the patient experience and enabling providers to deliver care more swiftly.

Enhanced Real-Time Price Transparency

Health IT systems must upgrade to RTPB version 13 to provide immediate access to drug pricing information. This functionality empowers patients and providers to make informed decisions about care and expenses, fostering a more transparent healthcare system.

Improved Data Interoperability

The ability of systems or software to exchange and make use of patient information is at the heart of the HTI-2 proposed rule. It mandates the use of standardized APIs that ensure seamless data exchange across different health IT systems to promote better coordination and continuity of care.

In addition, the adoption of United States Core Data for Interoperability (USCDI) version 4 will standardize the types of data exchanged. Proposals for USCDI version 5 are due September 30, 2024.

Enhanced Patient Access

The rule also places a strong emphasis on patient access to health information by requiring health IT developers to ensure patients have easy and secure access to their health information through user-friendly interfaces. This will enable patients to manage their health more effectively and engage more fully in their care.

Stronger Privacy and Security Measures

With the increased emphasis on data sharing and patient access, the HTI-2 proposed rule also strengthens privacy and security requirements including advanced encryption and other security measures.

Updated Certification Criteria

New functionalities and performance metrics are part of the criteria health IT systems must meet to ensure they are equipped to handle current and future needs of the healthcare industry.

The HTI-2 proposed rule will have significant implications for roadmap development in 2025, 2026, and 2027. The scope and scale of the required changes will necessitate careful planning and phased implementation to ensure that all systems comply with the new standards and are fully capable of meeting the evolving demands of the healthcare landscape. By understanding these impacts, EHR and HIT vendors can better prepare for the challenges ahead and position themselves for success in this new regulatory environment.

Part 3: Parallel Regulatory Journeys

Navigating the regulatory landscape will require paying close attention to the interplay between CMS and ASTP/ONC rules. Here are some key points to consider:

Rulemaking complexity: The healthcare industry must keep track of numerous rules from both CMS and ONC/ASTP, each with its own requirements and timelines.

Publication cadence: Forecasting changes can be challenging due to the varying schedules of rule publication and updates.

Comment periods: The different public feedback periods can lead to difficulties in harmonizing stakeholder input.

Clashing requirements: Deadlines from ASTP/ONC and CMS sometimes conflict, necessitating careful planning and coordination to ensure compliance with both sets of regulations.

By understanding these parallel regulatory journeys, EHR and HIT vendors can better navigate the complexities of compliance while leveraging opportunities to enhance their product offerings and improve patient outcomes. The alignment of CMS and ASTP/ONC rules represents a concerted effort to drive interoperability and efficiency in healthcare, ultimately benefiting all stakeholders in the healthcare ecosystem.

Roadmap Impact: Modeling for Parallel Rules

Implementing new e-prescribing and interoperability standards presents significant challenges and opportunities for EHR and HIT vendors. A well-structured roadmap is essential for effectively navigating these changes.

This section outlines the key phases and activities over the next few years, providing a clear framework to assess impacts, update systems, and ensure compliance with the latest CMS and ASTP/ONC regulations. By following this roadmap, vendors can strategically plan for the transition, keeping ahead of regulatory requirements while enhancing their product offerings and client satisfaction.

Timeline and Recommendations

Fall 2024

Assess Impacts

It's crucial for EHR and HIT vendors to thoroughly assess the impacts of upcoming regulatory changes. Key activities during this period include:

- **Finish HTI-1 implementations:** Complete any remaining tasks related to the HTI-1 requirements to ensure compliance and set a solid foundation for future updates.
- **CY25 roadmap reconstruction:** Revise and reconstruct your 2025 roadmap to incorporate the latest regulatory changes and prepare for the new standards.
- **HTI-2 final rule expected:** Stay alert for the release of this rule, which will provide detailed requirements and timelines for the next phase of interoperability and e-prescribing standards.

Early 2025

Focus on HTI-1

Your emphasis will be on meeting HTI-1 interoperability requirements and preparing for the forthcoming HTI-2 standards:

- **HTI-1 interoperability requirements:** Ensure all interoperability requirements from HTI-1 are fully implemented and operational.
- **Update CY26 roadmap after HTI-2 final rule:** Once the HTI-2 final rule is published, update your 2026 roadmap to reflect the new requirements and timelines.
- **Client upgrades:** Begin upgrading client systems to comply with the new HTI-1 standards and prepare them for future changes.

Mid- to Late 2025

E-Prescribing Phase 1

During this period, focus will shift to the initial phase of the new e-prescribing standards:

- **Development for F&B version 60:** Start developing updates to support this new version, ensuring your systems can handle the new standards.
- **Development for RTPB version 13:** Implement this version to provide real-time benefit information at the point of care.
- **Development for HTI-2 (estimated):** To meet compliance deadlines, begin development work based on the estimated requirements of HTI-2.
- **Update certifications:** Ensure all necessary certifications are updated to reflect the new standards.
- **Client upgrades:** Continue upgrading client systems to support the new e-prescribing standards and interoperability requirements.

Early 2026

E-Prescribing Phase 2

In early 2026, the focus will be on the second phase of e-prescribing standards implementation:

- **NCPDP SCRIPT Standard 2023011:** Implement this standard, ensuring your systems support updated prescribing, electronic prior authorization, and medication history standards.
- **Update certifications:** Obtain any additional certifications required for the new standards.
- **Last mile HTI-2 (estimated):** Complete the final steps of HTI-2 implementation to ensure full compliance with all interoperability and data exchange requirements.
- **Client upgrades:** Perform the final upgrades for client systems to ensure they fully comply with the new standards.

2027

Full Adoption

Establish a plan for ongoing upgrades and maintenance to ensure continued compliance with evolving standards and to address any emerging needs or improvements.

Methodical Approach to Regulatory Compliance

Navigating the evolving landscape of regulatory changes from CMS and ASTP/ONC is no small feat. Each phase—from assessing impacts and updating roadmaps to developing new standards and ensuring full adoption—will necessitate meticulous planning, robust development, and seamless execution.

To tackle these challenges effectively, a systematic approach to regulatory compliance is essential:

- Review the new regulations thoroughly to identify all impacted workflows. Understanding the full scope of the changes is crucial for effective planning and implementation.
- Streamline and consolidate workflows where possible to build flexibility into your roadmap. This ensures that your systems can more easily adapt to future changes.
- Establish feedback loops with clinicians to ensure compliance efforts are not just about "checking the box." Their insights can help create more practical and user-friendly solutions.
- Consider forming strategic partnerships with firms specializing in regulatory compliance to accelerate your efforts and help integrate workflow improvements seamlessly.

For many EHR and HIT vendors, managing these intricate regulatory requirements in-house can be overwhelming. Staying ahead of compliance deadlines, achieving necessary certifications, and continuously upgrading client systems can stretch resources thin and divert focus from core business operations and innovation.

This is where outsourcing can play a crucial role. Partnering with specialized firms with expertise and experience in handling healthcare regulations can alleviate the pressure on internal teams. These experts can provide the technical know-how, strategic insights, and dedicated focus required to navigate regulatory complexities efficiently. By leveraging their capabilities, vendors can ensure compliance while maintaining the quality and functionality of their product offerings.

Outsourcing regulatory work can also lead to better workflow efficiencies and patient care outcomes. With external experts handling compliance intricacies, internal teams can concentrate on enhancing user experience, developing innovative features, and improving overall system performance. This synergy can result in more robust, compliant, and user-friendly solutions that ultimately benefit both healthcare providers and patients.

Final Thoughts

While the path to regulatory compliance is challenging, it also offers opportunities for growth and improvement. By strategically outsourcing complex regulatory tasks and adopting a methodical approach, EHR and HIT vendors can confidently navigate the regulatory storm, ensuring they meet all requirements while continuing to innovate and deliver exceptional value to their clients.

With the right strategies and partnerships, vendors can turn regulatory challenges into opportunities for advancing healthcare technology and improving patient outcomes.

Barger urges EHR and other HIT vendors to use this period of heavy regulatory activity as an opportunity to meaningfully impact clinical workflows: "Don't just check the box," he says.

"There are three major rules that will impact your development cycle over the next three years," he added.

"I really encourage a long roadmap, and don't wait to start. If you need help, consider partnerships—they might be your best bet for how you can do this with a long implementation roadmap for your health systems."

Resource Links

Centers for Medicare & Medicaid Services (CMS) Final Rule

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule

About DrFirst

Since 2000, healthcare IT pioneer DrFirst has empowered providers and patients to achieve better health through intelligent medication management. We improve healthcare efficiency and effectiveness by enhancing e-prescribing workflows, improving medication history, optimizing clinical data usability, and helping patients start and stay on therapy.

DrFirst has won over 25 awards for excellence and innovation, including winning Gold in the prestigious Edison Awards in 2023, recognizing our game-changing use of clinical-grade AI to streamline time-consuming healthcare workflows and prevent medication errors. Our solutions are used by more than 350,000 prescribers, 71,000 pharmacies, 270 EHRs and health information systems, and over 2,000 hospitals in the U.S. and Canada. To learn more, visit DrFirst.com, and follow us on LinkedIn or @DrFirst on X.