

NEW AND UPDATED ELECTRONIC PRESCRIPTION FUNCTIONALITY

ADDED AND REVISED CERTIFICATION CRITERIA FOR HEALTH IT

[The Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization \(HTI-4\) Final Rule](#) has established updates and additions to the ONC Health IT Certification Program certification criteria related to electronic prescribing and real-time prescription benefit capabilities. Through ongoing collaboration and coordination with CMS, ASTP/ONC is committed to advancing interoperability for patients, health care providers, and payers to ease administrative burdens. This final rule is a critical step in these efforts.

WHAT DEVELOPERS SHOULD EXPECT

Electronic Prescribing Requirements

If a developer's product(s) is already certified to § 170.315(b)(3), the developer has a transition period to update their product to the new requirements. The following updates are required by **December 31, 2027**:

- Update to support the NCPDP SCRIPT standard version 2023011.
- Update to support the appropriate NDC and RxNorm minimum standard code sets.
- Demonstrate capabilities to support required electronic prior authorization (ePA) transactions, previously listed as optional within the criterion.
- Certify to the Real-time prescription benefit criterion as part of new dependencies outlined in the Certification Program.

Real-Time Prescription Benefit Requirements

Developers only need to certify to § 170.315(b)(4) by December 31, 2027 in two scenarios:

- 1) The certified Health IT Module is already certified to § 170.315(b)(3) and therefore must be certified to the RTPB criterion as a dependency of the certification.
- 2) The Health IT Module aims to maintain adherence to the criteria outlined in the [Base EHR definition](#).

For developers not yet certified to the electronic prescribing criterion, there are no time-bound considerations for certification.

SUMMARY OF UPDATES

Revised Electronic Prescribing Criterion

ASTP/ONC updated the baseline standard for the § 170.315(b)(3) Electronic prescribing certification criterion. The § 170.315(b)(3) Electronic prescribing criterion now incorporates the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2023011. ASTP/ONC adopted the standard last year in collaboration with CMS to support nationwide interoperability between prescriber systems and Part D sponsors. We also now require that prescriber systems support functionality for electronic prior authorization of prescriptions, which until now was optional in the Program.

Comparison of Transactions in § 170.315(b)(3) based on NCPDP SCRIPT Standard Version

Transactions	NCPDP SCRIPT Version 2017071 (Expires January 1, 2028)	NCPDP SCRIPT Version 2023011 (Required by December 31, 2027)
New prescriptions (NewRx).	Required for certification	Required for certification
Receive fill status notifications (RxFill).	Required for certification	Required for certification
Request and receive medication history (RxHistoryRequest, RxHistoryResponse).	Required for certification	Required for certification
Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).	Required for certification	Required for certification
Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).	Required for certification	Required for certification
Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).	Required for certification	Required for certification
Relay acceptance of a transaction back to the sender (Status).	Required for certification	Required for certification
Respond that there was a problem with the transaction (Error).	Required for certification	Required for certification
Respond that a transaction requesting a return receipt has been received (Verify).	Required for certification	Required for certification
Electronic prior authorization (PAInitiationRequest, PAINitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse).	Optional for certification	Required for certification
PANotification	Not required for certification	Required for certification
New prescription requests (NewRxRequest, NewRxResponseDenied).	Optional for certification	Not required for certification
RxTransferRequest, RxTransferResponse, RxTransferConfirm, and RxFillIndicatorChange.	Optional for certification	Not required for certification
Request to send an additional supply of medication (Resupply).	Optional for certification	Not required for certification
GetMessage.	Optional for certification	Not required for certification

Transactions	NCPDP SCRIPT Version 2017071 (Expires January 1, 2028)	NCPDP SCRIPT Version 2023011 (Required by December 31, 2027)
Communicate drug administration events (DrugAdministration).	Optional for certification	Not required for certification
Recertify the continued administration of a medication order (Recertification).	Optional for certification	Not required for certification
Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).	Optional for certification	Not required for certification

New Real-Time Prescription Benefit Criterion

The HTI-4 Final Rule adopts new § 170.315(b)(4) Real-time prescription benefit (RTPB) certification criterion, which focuses on functionality needed to support real-time prescription benefit checks for cost and coverage information for prescription drugs, vaccines and medical supplies.

Furthermore, ASTP/ONC has added § 170.315(b)(4) to the Base EHR definition on and after January 1, 2028.

Health IT Modules must enable users to:

- Send RTPBRequest transactions: Request patient-specific prescription benefit information, estimated cost information, and alternative products
- Receive RTPBResponse transactions: Receive the requested benefit information in response
- Handle mandatory and situational segments: Support all required transaction segments and data elements per NCPDP RTPB standard version 13

To align with § 170.315(b)(4) standard requirements, Health IT Modules must:

- Use NCPDP RTPB standard version 13 as adopted in 45 CFR 170.205(c)
- Support XML format only for transactions (EDI format not required)
- Use RxNorm (45 CFR 170.207(d)(1)) and National Drug Codes (NDC) (45 CFR 170.207(d)(2))

Health IT Modules must display information in human-readable format including:

- Patient-specific prescription benefit information
- Estimated cost information (patient out-of-pocket costs)
- Alternative products

HOW DO ELECTRONIC PRESCRIBING AND RTPB CRITERIA INTERACT?

Real-time prescription benefit functionality is closely related to electronic prescribing functionality, which provides the basic workflow within which a provider may seek to identify information about a patient's coverage for a certain prescription before transmitting that electronic prescription to the pharmacy. HTI-4 Final Rule established a connection between § 170.315(b)(3) Electronic prescribing and § 170.315(b)(4) RTPB criteria with a dependency outlined in § 170.550(g)(6). For developers already certified to § 170.315(b)(3) and wishing to remain certified to

§ 170.315(b)(3) on and after January 1, 2028, you must update and provide to your customers a Health IT Module that is also certified to § 170.315(b)(4). If you are not yet certified to § 170.315(b)(3) but are planning to do so after October 1, 2025, you must also complete certification to the § 170.315(b)(4) criterion.

Despite this established dependency, the electronic prescribing certification criterion is not included as part of the current Base EHR definition, while the RTPB criterion has been added as a required criterion for the Base EHR on and after January 1, 2028.

To reiterate, whenever a developer updates or adds § 170.315(b)(3) to their certified product following effective date, the developer will also be expected to also certify to § 170.315(b)(4) at that time. As outlined in regulation, developers already certified to § 170.315(b)(3) are required to update their products to new § 170.315(b)(3) requirements by December 31, 2027.

REGULATORY ALIGNMENT WITH CMS

These updates demonstrate ASTP/ONC's ongoing coordination with CMS in efforts to advance electronic capabilities supporting providers and patients at the point of care. Section 1860D-4(o) of the [21st Century Cures Act](#) requires incorporation of real-time benefit tools (RTBTs) within both the Medicare Part D prescription drug program and the Certification Program. Furthermore, the Consolidated Appropriations Act (CAA) of 2021 added new requirements for both CMS and ASTP/ONC related to real time electronic identification of prescription benefit information.

By adding the RTPB certification criterion in the Certification Program, ASTP/ONC has implemented complementary requirements to the Medicare Part D program to enable access to prescription benefit information at the point of care. Both requirements are based on common standards for real-time prescription benefit exchange developed by the NCPDP and align provider and payer requirements around real-time prescription benefit capabilities.