Report of the Electronic Prior Authorization Work Group

Submitted to the Chairs of the Senate Committees on Commerce and Labor, and Education and Health; and the House Committees on Commerce and Energy and Health, Welfare and Institutions, pursuant to Chapters 474 and 475, Acts of Assembly – 2023 Session





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TRANSMITTED VIA EMAIL

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BUREAU OF INSURANCE

The Honorable Richard L. Saslaw Chair, Commerce and Labor Committee Senate of Virginia

The Honorable L. Louise Lucas Chair, Education and Health Committee Senate of Virginia

The Honorable Terry G. Kilgore Vice Chair, Commerce and Energy Committee Virginia House of Delegates

The Honorable Robert D. Orrock, Sr. Chair, Health, Welfare and Institutions Committee Virginia House of Delegates

Dear Senators Saslaw and Lucas and Delegates Kilgore and Orrock:

Pursuant to Chapters 474 and 475 (HB 1471 and SB 1261, respectively), Virginia Acts of Assembly – 2023 Session, the State Corporation Commission, in coordination with the Secretary of Health and Human Resources, submits this Report of the Electronic Prior Authorization Work Group on behalf of the participating stakeholders.

While the Bureau of Insurance and the Health and Human Resources Secretariat staffed the work group and served as facilitators, this report represents the perspectives of the participating stakeholders.

Respectfully submitted,

Scott A. White Commissioner of Insurance

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Executive Summary

During its 2023 Session, the General Assembly re-enacted amended provisions first adopted in 2022,¹ designed to automate the prior authorization process for prescription drugs and provide real-time, patient-specific benefit information to enrollees and contracted providers for covered prescription drugs, beginning July 1, 2025. These amendments have been codified in §§ <u>38.2-3407.15:2</u> and <u>38.2-3407.15:7</u> of the Code of Virginia (Code).

The General Assembly also extended the term of the Electronic Prior Authorization Work Group through November 1, 2025, and expanded its charge to include assessing progress towards electronic prior authorization ("ePA") for prescription drugs and provider access to patient-specific prescription benefit information in real-time, evaluating the use of ePA for certain medical services, establishing a process for a real-time link to prescription coupons at the point of prescribing and recommending any statutory changes related to this charge.

This report represents the perspective and consensus of participating stakeholders, including those of the Virginia Association of Health Plans, Medical Society of Virginia, Virginia Hospital and Healthcare Association, Virginia Pharmacists Association, and other interested stakeholders. The Bureau of Insurance of the State Corporation Commission, in coordination with the Health and Human Resources Secretariat, staffed and served as facilitator of the work group.

The key findings and recommendations of the work group are as follow:

1. The work group recommends that impacted stakeholders conduct a member readiness survey and engage in associated member outreach. While affected payers and providers are making progress towards implementing ePA and real-time prescription benefit (RTPB) information, and no specific impediments have been identified, implementation may prove more challenging for small health plans, regional healthcare systems, independent non-health system facilities, and certain practitioners.

2. While eager to have ePA for medical services, the work group does not recommend mandating it in Virginia prior to the standardization of technical requirements at the federal level for Medicare Advantage and other government payer programs. In addition, the work group recommends that any future mandates for medical ePA for the private commercial market align with those ultimately adopted at the federal level to avoid creating a fragmented system that may be costly and inefficient.

3. The work group recommends the General Assembly not address prescription coupon functionality until ePA and real-time benefit tools (RTBT) for prescription drugs have been implemented and fully integrated into electronic health records (EHR).

4. Finally, the work group considers it prudent to wait until 2024 to see if and when the Centers for Medicare and Medicaid Services (CMS) names an RTPB standard for Medicare Part D before moving forward with any legislative proposals.

1. Introduction

During its 2023 Session, the General Assembly re-enacted amended provisions first adopted in 2022, designed to automate the prior authorization process for prescription drugs and provide real-time patient-specific benefit information to enrollees and contracted providers for covered prescription drugs, beginning July 1, 2025. These amendments have been codified in §§ <u>38.2-3407.15:2</u> and <u>38.2-3407.15:7</u> of the Code.

The National Council for Prescription Drug Programs (NCPDP), a not-for-profit, nationally accredited, standards development organization, describes prior authorization as "the process that is used to request coverage of a specific medication for a specific patient.² Automating the prior authorization process through ePA will help streamline and accelerate the disposition of prior authorization requests.³

In its 2022 report, the work group recommended that it be continued through July 1, 2025, to serve as "a forum ... to meet and assess progress towards implementing electronic prior authorization and real-time cost benefit information for prescription drugs, ... [and recommend] any last-minute changes to facilitate implementation."⁴ The General Assembly extended the term of the ePA Work Group through November 1, 2025, and expanded its charge.

The expanded charge requires the work group to:

- i. assess progress toward implementing ePA and real-time (cost) benefit information for prescription drugs, as required by this act,⁵ including monitoring and evaluating the impact of any state or federal developments;
- ii. evaluate and make recommendations to establish a process for ePA for surgery and other procedures in order to maximize efficiency and minimize delays;
- iii. evaluate and make recommendations to establish an online process for a realtime link at the point of prescribing for any available prescription coupons; and
- iv. make recommendations for any additional statutory changes required to facilitate such implementation or to establish such processes.

The work group includes representatives of the Virginia Association of Health Plans, Medical Society of Virginia, Virginia Hospital and Healthcare Association, Virginia Pharmacists Association, and other interested stakeholders. The Bureau of Insurance, in coordination with the Health and Human Resources Secretariat, staffed and served as facilitator of the work group. This is the first of three additional reports the work group is required to file with the Chair of the Senate Committees on Commerce and Labor and Education and Health; and Chair of the House Committees on Commerce and Energy and Health, Welfare and Institutions. The reports are due by November 1, 2023, 2024, and 2025.

2. Meetings

The work group met in June, July, August, and September 2023.

<u>June 7</u>

This meeting focused on federal and state developments related to ePA for prescription drugs. Presentations were received from the Office of the National Coordinator for Health Information Technology (ONC); the CMS Division of Part D Policy; and CoverMyMeds.

<u>July 20</u>

This meeting focused on federal developments related to ePA for medical services under federal programs such as Medicare Advantage, including developments integral to the adoption of the <u>Health Level Seven® (HL7®) International</u> Fast Health Interoperability Resources (<u>FHIR®</u>) standard⁶ for the electronic exchange of medical information. A CMS representative presented an overview of the proposed interoperability and prior authorization rule;"⁷ and the Use Case Coordinator for <u>CodeX</u> Prior Authorization in Oncology with Point-of-Care Partners presented on two FHIR <u>Accelerators</u>: the <u>HL7 Da Vinci Project</u> and <u>CodeX</u>.⁸

August 31

This meeting focused on the charge related to prescription coupons as well as the role and perspective of EHR software vendors in the implementation of ePA and RTBTs for prescription drugs and medical services. A representative in standards development with the NCPDP provided background information on the prescription coupon proposal. Two EHR software vendors presented: teams from Epic and athenahealth shared their perspectives on health plan and provider readiness and the complexities involved in implementing ePA and RTBTs for both prescription drugs and medical services. The presentation from athenahealth included a demonstration of its premium EHR solution.

September 26

This meeting focused on consideration of the work group's draft 2023 report. Revisions were suggested and subsequently incorporated into a final draft approved by the work group.

3. Findings and Recommendations

Based on presentations, discussions, and stakeholder input, the work group makes the following findings and recommendations for 2023.

A. Prescription Drugs

Findings:

A1: Representatives of health plans, healthcare systems, and providers indicate that progress is being made in the implementation of ePA for prescription drugs and real-time (cost) benefit information for prescription drugs. Although it is still early, they have not identified any specific impediments that might delay implementation. Large health plans – driven by the national mandate to automate prior authorization for Medicare Part D plan sponsors – and health care systems, should be able to move forward with implementation relatively smoothly. The work group considers that implementation could prove more challenging for small health plans, regional healthcare systems, independent non-health system facilities, and certain practitioners.

- According to the Virginia Association of Health Plans, its member plans are on track for implementation by July 2025. Many of its member health plans already provide resources through EHR or are taking steps to complete this piece of the puzzle. These health plans account for the majority of the private commercial health insurance market in Virginia
- According to the Virginia Hospital and Healthcare Association, its members are on track for implementation using the NCPDP SCRIPT standard and RTBTs by July 1, 2025. Members are working with their EHR software vendors and various intermediaries to have the functionality the law requires in place, on time. The association expects carriers to make providers aware of the intermediaries and vendors they will use in accordance with the statutory requirement by July 1, 2024, to avoid delays in establishing full connectivity and functionality.
- According to the Medical Society of Virginia, the physician community will continue to monitor progress in implementation in the run up to July 2025. Technological change is always difficult for those providers with limited resources or technological access. Updates will be provided to the work group in 2024.

A2: Based on testimony received by the workgroup from EHR software vendors, there should be adequate lead time for affected entities to respond to any issues that arise since the technologies and processes are available to support implementation within a six-to-eight-month timeframe, and possibly sooner. However, the work group recognizes the complexities involved in implementing ePA and RTBTs.

A3: Federal regulations require Medicare plan sponsors and providers participating in Part D that process prior authorizations electronically to use the NCPDP SCRIPT

standard.⁹ A CMS proposal that would have required use of a newer version of the NCPDP SCRIPT standard by January 1, 2025, was omitted from the final version of a rule adopted earlier this year and is expected to be addressed in a subsequent rulemaking.¹⁰

A4: Medicare Part D plan sponsors currently are required to implement "an electronic real time benefit tool capable of integrating with at least one prescriber's e-prescribing system or electronic health records."¹¹ A CMS proposal that would have required the NCPDP's RTPB standard be the standard for prescriber RTBTs supported by Medicare Part D plan sponsors, beginning January 1, 2025, was omitted from the final version of a rule adopted earlier this year and is expected to be addressed in subsequent rulemaking.¹² The work group is closely monitoring CMS action on this, since any delay in naming the RTPB standard could push the date of implementation for Part D plan sponsors beyond January 1, 2025, with possible implications for implementing RTBTs in Virginia by July 1, 2025, should Virginia choose to align with federal standards.

A5: In Virginia, health plans must respond to urgent prior authorization requests for prescription drugs within 24 hours and non-urgent requests within two business days.¹³ By comparison, plan sponsors under the Medicare Part D prescription drug plan must respond to expedited (i.e., urgent) prior authorization requests within 24 hours and standard (i.e., non-urgent) requests within 72 hours.¹⁴

Recommendations:

A1: The work group recommends that Virginia continue to monitor parallel federal developments related to ePA for prescription drugs and RTBTs as an "early warning" system for identifying or resolving potential implementation issues in Virginia and to stay abreast of any developments that might require a response to ensure consistency.

A2: Since the workflow horizon seems to be about six months, the work group recommends that participating stakeholder groups that have not yet done so, begin educating their members on ePA and RTBTs for prescription drugs so they can integrate these into their workflow in time to meet required implementation dates or pursue any available hardship option.

A3: The work group recommends that stakeholder organizations with members subject to Virginia's July 1, 2025, deadline for implementing ePA and RTBTs for prescription drugs conduct a readiness survey and engage in associated member outreach in 2024.

B. Medical Services

Findings:

B1: On December 6, 2022, the CMS issued a proposed rule entitled "Advancing Interoperability and Improving Prior Authorization Processes." The proposed rule would automate prior authorization for impacted payers under Medicare Advantage plans, Medicaid managed care and fee-for-service plans, Children's Health Insurance Program managed care and fee-for-service plans, and Qualified Health Plans on the Federally Facilitated Exchanges (FFE), effective January 1, 2026, via a specific application interface (i.e., PARDD API). For all but Qualified Health Plans on the FFEs, payers would be required to respond to standard (i.e., non-urgent) prior authorization requests within 7 days (reduced from current 14) and expedited (i.e., urgent) prior authorization requests within 72 hours.¹⁵

B2: The CMS is part of a national public-private initiative to develop the technical standards necessary to support ePA implementation for medical services, most notably the FHIR standard for the electronic exchange of medical information.

B3: As of now, the ONC has not put forth changes to the Health IT Certification Program concerning the certification, adoption, and utilization of specific technical standards for ePA applicable to medical services and products covered by Medicare Advantage plans and other governmental payer programs.

B4: The technology is available to support medical ePA; however, implementation is the challenge. As one presenter noted, "Payers have inconsistent requirements, providers have inconsistent documentation, and technical standards are not yet mature."¹⁶ In short, it is "extraordinarily complex to implement," according to a large EHR software vendor.¹⁷

B5. Transitioning from medical ePA under federal programs to medical ePA in the private commercial market should be relatively seamless, although integrating all the pieces is still considered a heavy lift on the payer side. While federal programs and private markets have parallel systems, with similar standards applied in a similar manner, payers have challenges in infrastructure, data configurations and rules.

Recommendations:

B1. While eager to have fully ePA processes for medical services, the work group does not recommend mandating ePA in Virginia prior to the standardization of technical requirements at the federal level for impacted payers under Medicare Advantage and other government programs.

B2. The work group recommends that technical requirements for any future mandates for medical ePA for the private commercial market in Virginia align with those ultimately adopted at the federal level to avoid creating a fragmented system that may be costly and inefficient.

B3. The work group stresses the importance of ensuring translation between the NCPDP SCRIPT Standard (prescription benefit) and HL7® FHIR standards (medical benefit) to enable integration of both standards by affected health plans.

C. Prescription Coupons

Findings:

C1: The NCPDP has no current plans to develop a standard for processing prescription drug coupons. According to the NCPDP, updating an existing standard could take six to eight months, while developing a new standard could take a minimum of two years.¹⁸

C2. Any person may petition the NCPDP to develop or modify a standard for integrating prescription coupons into a provider's workflow. No formal request has been made.

C3: At least one EHR software vendor already integrates coupons into the provider workflows at the point of prescribing. Third-party applications that integrate into an EHR during the patient encounter also are available.

C4. There is no single repository or source of coupon information. Much of it is outside of the workflow of providers and pharmacists, making identification burdensome and time-consuming. One stakeholder described it as "unorganized and messy."¹⁹

Recommendations:

C1: The work group recommends that the General Assembly not address this functionality until ePA and RTBTs for prescription drugs are implemented and fully integrated into EHRs.

C2: The work group recommends further exploration of the extent to which EHRs already include this functionality and how its availability may influence future policy recommendations.

D. Any Additional Statutory Changes

Recommendations:

The work group does not recommend any statutory changes for consideration during the 2024 Session of the General Assembly.

4. Looking Ahead to 2024

The work group agreed to defer action on several proposals requiring legislation until its 2024 cycle of meetings. In keeping with its recommendation that Virginia align its technical standards and timeframes with those adopted at the federal level, the work group considers it prudent to wait until 2024 to see if and when the CMS names an RTPB standard for Medicare Part D before moving forward with any legislative proposals. While other proposals may emerge in 2024, those suggested by one or more work group members as part of this report include the following:

- Adjustment to RTBT implementation timeframes in Virginia necessitated by any changes to federal Medicare Part D timeframes;
- Provision for hardship waivers for small health plans similar in concept to hardship waivers currently available to eligible providers;
- Evaluation of prior authorization response timeframes following implementation of ePA for prescription drugs; and
- Adjustment to statutory references to the NCPDP SCRIPT standard in light of newer versions.

Appendix A. Electronic Prior Authorization Work Group Resources and Stakeholders

State Government Resources

State Corporation Commission Virginia Department of Medical Assistance Services Virginia Department of Health Virginia Health and Human Resources Secretariat

Interested Stakeholder Organizations

Acentra Health Aetna America's Health Insurance Plans (AHIP) Anthem Arthritis Foundation Association for Accessible Medicines athenahealth CareFirst BlueCross BlueShield Cigna CoverMyMeds HCA Healthcare McKesson Medical Society of Virginia National Council for Prescription Drug Programs Pharmaceutical Care Management Association Pharmaceutical Research and Manufacturers of America **Point-of-Care Partners** Prescryptive Sentara Surescripts Virginia Academy of Family Physicians Virginia Association of Health Plans Virginia Hospital and Healthcare Association Virginia Pharmacists Association

End Notes

¹ Chapters <u>474</u> and <u>475</u>, (HB 1471 and SB 1261, respectively) Virginia Acts of Assembly – 2023 Session.

² "NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA): Fact Sheet," January 2015. "Generally, the prescriber requests the authorization from a "Payer" (health plan, processor, or Pharmacy Benefit Manager). The Payer determines whether it will pay for the medication based on a number of factors, such as medical necessity, prior treatment, clinical indications, and total cost of therapy. This process has historically been handled via facsimile exchange of information or telephone call, and only recently via paver-specific web portals."

³ State Corporation Commission, <u>Report of the Electronic Prior Authorization Work Group</u>, November 1, 2022, at 7.

⁴ State Corporation Commission, Report of the Electronic Prior Authorization Work Group, November 1, 2022, at 3.

⁵ Chapters <u>474</u> and <u>475</u>, (HB 1471 and SB 1261, respectively) Virginia Acts of Assembly – 2023 Session.

⁶ The FHIR standard is an open-source "set of rules and specifications for healthcare data exchange" (exchanging EHRs) developed by Health Level Seven (HL7) that has been rapidly adopted. "Fast Healthcare Interoperability Resources," wikipedia (link), viewed on October 10, 2023. "FHIR is important because it acts as a connector to bridge the gaps between all parties that need access to patient data," akana (link), viewed on October 18, 2023.

CMS-0057-P, "Advancing Interoperability and Improving Prior Authorization Processes," December 12, 2022, 87 FR 76238. ⁸ For more information, visit the <u>Da Vinci Video Presentations</u> page to view "Reducing Prior Authorization Burden and Improving Oncologic Care with HL7 FHIR," a presentation given by both Accelerators on August 23, 2023. ⁹ <u>42 CFR 423.160(a)(1)</u>, <u>42 CFR 423.160(a)(2)</u> and <u>42 CFR 423.160(b)(8)</u>.

¹⁰ CMS-4201-P, 87 FR 79452, 79548; published December 27, 2022. The "Supplementary Information" for the final rule published April 5, 2023, states: "CMS intends to address all of the remaining proposals from the December 2022 proposed rule in subsequent rulemaking. Therefore, CMS plans to make provisions adopted in the subsequent, second final rule applicable to coverage beginning no earlier than January 1, 2025." CMS-4201-F, 88 FR 22120, published April 12, 2023.

¹¹ <u>CMS-4180-F</u>, 84 FR 23832, 23832, Medicare Advantage and Part D Drug Pricing Final Rule, published May 23, 2019. ¹² CMS-4201-P, 87 FR 79452, 79548; published December 27, 2022. The "Supplementary Information" for the final rule published

April 5, 2023, states: "CMS intends to address all of the remaining proposals from the December 2022 proposed rule in subsequent rulemaking. Therefore, CMS plans to make provisions adopted in the subsequent, second final rule applicable to coverage beginning no earlier than January 1, 2025." CMS-4201-F, 88 FR 22120, published April 12, 2023.

¹³ Title 38.2-3407.15:2 B 2, 3, and 4 of the Code of Virginia. (link)

14 42 CFR § 423.568(b)

¹⁵ CMS-0057-P, "Advancing Interoperability and Improving Prior Authorization Processes," published December 12, 2022, 87 FR 76238

¹⁶ Presentation by Epic to the Virginia Electronic Prior Authorization Work Group, August 31, 2023.

¹⁷ Presentation by Epic to the Virginia Electronic Prior Authorization Work Group, August 31, 2023.

¹⁸ Statement of Margaret Weiker with the NCPDP at the Virginia Electronic Prior Authorization Work Group meeting, August 31, 2023.

¹⁹ Statement from pharmacist John Seymour at the Virginia Electronic Prior Authorization Work Group meeting, August 31, 2023.