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 Labor and Commerce, and Health and Human Services, pursuant to Chapters 474 and 475, Acts of Assembly – 2023 Session

November 1, 2024

COMMONWEALTH OF VIRGINIA

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TRANSMITTED VIA EMAIL

The Honorable R. Creigh Deeds
Chair, Commerce and Labor Committee
Senate of Virginia

The Honorable Ghazala F. Hashmi
Chair, Education and Health Committee
Senate of Virginia

The Honorable Jeion A. Ward
Chair, Labor and Commerce Committee
Virginia House of Delegates

The Honorable Mark D. Sickles
Chair, Health and Human Services Committee
Virginia House of Delegates

Dear Senators Deeds and Hashmi and Delegates Ward and Sickles:

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 2024 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 enacted SB 1261 and HB 1471, extending the Electronic Prior Authorization (ePA) Work Group through November 1, 2025, and expanding its charge to include (i) assessing progress towards ePA for prescription drugs and provider access to patient-specific real-time prescription benefit (RTPB) information, (ii) evaluating the use of ePA for surgery and other procedures, (iii) evaluating and making recommendations for establishing a process for a real-time link to prescription coupons at the point of prescribing, and (iv) making recommendations for any additional statutory changes required to facilitate implementation or to establish such processes.

As part of its charge, the work group has sought to ensure that carriers and providers operate under a unified and consistent set of technical standards and requirements when processing ePA requests for prescription drugs and medical items and services in both the public and private health insurance marketplace. The national mandate for Medicare and Medicaid plan sponsors and payers to automate prior authorization is driving progress towards this end. Consequently, as it maps out a plan for implementing ePA in the private commercial market in Virginia, the work group is closely monitoring parallel federal developments for future alignment.

During this reporting period, several major rules have been proposed and adopted at the federal level to advance ePA. Each has been considered by the work group in making the following consensus recommendations:

1. Virginia should move forward with the implementation of ePA and RTPB processes for prescription drugs effective July 1, 2025, as required in §§ 38.2-3407.15:2 and 38.2-3407.15:7 of the Code, while impacted stakeholder groups should consider launching an informational campaign to inform and educate their members. As a corollary, the statutory undue hardship waiver in § 38.2-3407.15:2 B 17 must be available to qualifying providers.

2. Virginia should align its technical standards and requirements for medical ePA (currently encompassing medical “items and services” in relevant federal rules) for the private commercial health plans and providers with those ultimately adopted at the federal level to avoid creating a fragmented and inefficient system. While significant progress is being made at the federal level and among impacted payers and providers, more work remains to be done before Virginia should require implementation. The work group recommends the General Assembly consider extending the work group’s term to November 1, 2028, for the purpose of continuing to serve as a forum for monitoring anticipated federal developments and assessing progress over the next year towards implementation of medical ePA; assessing industry readiness; evaluating policies that support the implementation of ePA for medical items and services; and, by November 1, 2025, communicating a date certain to the General Assembly for private health plans and providers to implement medical ePA.

3. The work group recommends tabling further consideration of establishing an online process for a real-time link at the point of prescribing for any available prescription coupons until full implementation and integration of ePA and RTPB tools for prescription drugs.

4. Within a scope consistent with federal electronic prior authorization rulemaking, task the work group with evaluating and recommending policy proposals that will support the effective and efficient adoption of ePA for medical items and services.

1. Introduction and Purpose

During its 2023 Session, in SB 1261 and HB1471,[1] the General Assembly re-enacted amended provisions first adopted in 2022, designed to automate the prior authorization process for prescription drugs and provide patient-specific RTPB information to enrollees and contracted providers for covered prescription drugs, beginning July 1, 2025. These amendments have been codified in §§ 38.2-3407.15:2 and 38.2-3407.15:7 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] Based on a readiness survey developed through the work group, albeit with a very limited response, it appears Virginia's health plans and providers are processing a large percentage of prior authorization requests electronically.

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 work group through November 1, 2025, and expanded its charge 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 real-time 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.

As part of its charge, the work group has sought to ensure that carriers and providers operate under a unified and consistent set of technical standards and requirements when processing electronic prior authorization requests for medical services and for prescription drugs in both the public and private health insurance marketplace. Progress towards this end is being driven by the national mandate for Medicare and Medicaid plan sponsors and payers to automate prior authorization. In Virginia, these two programs account for nearly one-third of the overall market.[6] Consequently, as it maps out a plan for implementing ePA in the private employer-based commercial market in Virginia, the work group is closely monitoring parallel federal developments for future alignment.

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 Secretary of Health and Human Resources, staffed and served as facilitator of the work group.

This is the third in a series of four annual reports the work group is required to produce and file with the Chairs of the Senate Committees on Commerce and Labor and Education and Health; and Chairs of the House Committees on Labor and Commerce and Health and Human Services.[7] This report is due by November 1, 2024, with the final annual report due November 1, 2025.

2. Summary of Meetings

The work group met in May, June, August, and September during the 2024 reporting period.

May 21

The work group received federal updates from the Centers for Medicare and Medicaid Services (CMS) on ePA and RTPB for Medicare Part D and a presentation on the recently finalized rule entitled, “Advancing Interoperability and Improving Prior Authorization (CMS-0057-F).” Keeping abreast of federal developments is an important part of the work group charge. The work group also discussed the status of the proposed surveys developed by the Bureau in conjunction with the impacted stakeholder groups to gauge their membership’s readiness to implement ePA and RTPB for prescription drugs. The work group meeting also featured a discussion segment on the impact of federal developments on Virginia implementation of medical ePA.

June 17

The work group received a status report on the implementation readiness surveys for ePA and RTPB for prescription drugs. The stakeholder groups agreed to finalize and send the surveys with a submission date of July 26. Also, in the run-up to

implementation, the work group discussed plans for outreach by impacted stakeholder groups. Most of the meeting was devoted to a discussion of potential legislation related to implementation of prescription drug ePA and RTPB and medical ePA. In this regard, the work group considered its recommendations from the 2023 annual report.

August 20

The work group considered potential recommendations for each of its four charges, to include the implementation of ePA and RTPB for prescription drugs and medical ePA, an online process for handling prescription coupons, and any other statutory changes related to the substance of its work. It agreed on a way forward in each of these areas, with a subgroup agreeing to discuss the disposition of a broad set of general prior authorization proposals.

September 12

The work group considered its draft report, and after agreeing to two changes, adopted it for submission by the State Corporation Commission to the designated committee chairs in the General Assembly by November 1.

3. Findings and Recommendations

Based on presentations, discussions, and stakeholder input, the work group makes the following findings and recommendations for 2024.

A. Prescription Drugs

Findings:

A1. As recommended in the work group's 2023 annual report, impacted stakeholder groups surveyed health plan and provider associations to assess member readiness to implement ePA and RTPB for prescription drugs by July 1, 2025. According to the Virginia Association of Health Plans, large health plans appear ready to move forward with implementation. Of those responding to the survey, most were aware of the statutory requirements and had or expect to have the necessary processes in place. That sentiment was generally echoed by Virginia's healthcare systems. Although the Medical Society of Virginia received a very limited number of responses, most of those that did were not aware of the requirements but did expect to have the necessary access by July 1, 2025. The Virginia Dental Association found most member dentists and oral surgeons that responded were likewise not aware of the statutory requirements. However, it was noted that most prescription drugs prescribed by dentists and oral surgeons are not subject to prior authorization requirements. The physician community, among others, will continue to monitor progress in implementation in the run-up to July 2025. As the work group pointed out in its 2023 annual report, technological change is always difficult for those providers with limited resources or limited technological access.

A2. On June 17, 2024, the CMS published its "Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications" final rule (CMS-4205-F2). The new rule took effect on July 17, 2024. It requires Medicare Part D plan sponsors to use a newer version of the NCPDP SCRIPT standard than that currently in use, on or before January 1, 2028, when the current transition period allowing use of either version expires. Virginia's statutory ePA provision specifies use of the SCRIPT standard but does not specify a particular version.

A3. Also in 2024, the CMS finalized a rule adopting the NCPDP's RTPB standard as the standard for prescriber RTPB tools supported by Medicare Part D plan sponsors, beginning January 1, 2027. Therefore, the RTPB standard will be required to be implemented by private commercial health plans in Virginia prior to being required to be implemented by Medicare Part D plan sponsors.

A4. The Office of the National Coordinator (ONC) within the U.S. Department of Health and Human Services proposed the Health Data, Technology, and Interoperability (HTI-2) rule on August 5, 2024 – a rule that aligns[8] with the CMS interoperability and prior authorization final rule (CMS-0057-F). In addition to introducing new voluntary certification criteria for RTPB tools, the ONC rule calls on health plans to certify voluntarily that its technology can perform NCPDP SCRIPT ePA transactions.[9]

Recommendations:

A1. The work group recommends that Virginia move forward with the implementation of ePA and RTPB for prescription drugs effective July 1, 2025, as currently required in §§ 38.2-3407.15:2 and 38.2-3407.15:7 of the Code. As a corollary to this, the statutory undue hardship waiver in § 38.2-3407.15:2 B 17 must be available to qualifying providers.

A2. The work group recommends a clarifying revision in § 38.2-3407.15:2 B 16, as follows:

> "16. Require a carrier, beginning July 1, 2025, notwithstanding the provisions of subdivision 1 or any other provision of this section, to establish and maintain an online process that … (iv) links directly to real-time patient out-of-pocket costs for the prescription drug ~~office visit~~, considering copayment and deductible, …"

A3. The work group recommends that the impacted stakeholder groups collaborate on the development and launch of an informational campaign to inform and educate their membership on the implementation of ePA and RTPB for prescription drugs so that these can be integrated into their membership's workflows in time to meet the required implementation dates or pursue any available undue hardship waiver.

B. Medical Items and Services

Findings:

B1: On February 8, 2024, the CMS published its "Advancing Interoperability and Improving Prior Authorization" final rule (CMS-0057-F). These new regulations took effect on April 8, 2024. The rule requires 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 to implement and maintain a specific application programming interface (API) for ePA for medical "items and services" using the Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®) standard. Qualified Health Plans on state-based exchanges such as Virginia's are not subject to this requirement. However, CMS "encourage(s) . . . State-based Exchanges operating their own platform . . . to consider adopting similar requirements for [Qualified Health Plans] on their Exchanges."[10] The API must be populated with the payers' list of covered items and services, able to identify documentation requirements, and have the ability to support prior authorization requests and responses. It must be implemented by January 1, 2027. Other provisions, such as performance metrics for payers and certain prior authorization policies, must be implemented by January 1, 2026. While drugs[11] are excluded from the rule, CMS stated that "nothing in this final rule prohibits broader use of the required prior authorization API by impacted payers and we encourage them to do so to the extent permitted by law."[12] The CMS is expected to make drugs the subject of additional rulemaking, reportedly sometime in late fall 2024.

B2. Under the new rule, all payers other than Qualified Health Plans on the Federally Facilitated Exchanges must 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.[13] This compares to 3 calendar days for urgent requests and 14 calendar days for non-urgent requests under the Virginia Medicaid MCO[14] Contract. Once again, Qualified Health Plans on state-based exchanges such as Virginia's are not subject to this requirement.

B3. The CMS rules "complement the parallel efforts [by the ONC] to improve the access, exchange, and use of [electronic health information] through the . . . Health Information Technology Certification Program . . . ."[15] The ONC has been active in 2024, adopting a final rule (HTI-1)[16] that took effect on February 8, 2024, and publishing a proposed rule (HTI-2)[17] for public comment in the Federal Register on August 5, 2024 – both of which will advance interoperability and information exchange among health plans, providers, and patients. Specifically, HTI-1 updates the standards, specifications, and criteria for the ONC Health IT Certification Programs to "advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT,"[18] and includes electronic case reporting using FHIR®-based specifications, while HTI-2 calls for health plans and EHRs to certify voluntarily the prior authorization FHIR® APIs being developed by impacted payers pursuant to the CMS' interoperability and prior authorization final rule. If HTI-2 is adopted as written, health

plans will be asked to certify voluntarily that their technology can perform medical ePA via FHIR® APIs.[19]

B4. Although the new CMS interoperability and prior authorization rule requires plan sponsors and impacted payers to move forward with implementation of ePA for medical items and services under Medicare, Medicaid, and other government payer programs, remaining uncertainties surrounding implementation justify a pause for further monitoring and discussion by the work group before extending medical ePA to the private commercial market in Virginia. These uncertainties include plan readiness to implement the new FHIR® standard and implementation guides; plan and provider technical and infrastructure challenges, especially if having to implement in both markets simultaneously; exceptions that may be necessary on the medical side; and the way in which CMS chooses to address drugs covered under the medical benefit in rulemaking expected to begin in November 2024.

Recommendations:

B1. Virginia should align its technical standards and requirements for medical ePA (currently encompassing medical "items and services" in relevant federal rules) for private commercial health plans and providers with those ultimately adopted at the federal level to avoid creating a fragmented and inefficient system. While significant progress is being made at the federal level and among impacted payers and providers, more work remains to be done before Virginia should require implementation.

B2. The work group would ask the General Assembly to consider extending the work group's term to November 1, 2028, for the purpose of continuing to serve as a forum for monitoring anticipated federal developments and assessing progress over the next year towards implementation of medical ePA; assessing industry readiness; evaluating policies that support the implementation of ePA for medical items and services; and, by November 1, 2025, communicating a date certain to the General Assembly for private health plans and providers to implement medical ePA.

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.[20]

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.”[21]

Recommendations:

C1. The work group recommends tabling further consideration of establishing an online process for a real-time link at the point of prescribing for any available prescription coupons until full implementation and integration of ePA and RTPB tools for prescription drugs. At such time, the work group can revisit the extent to which EHRs already include this functionality and how its availability may influence future policy recommendations.

D. Any Additional Statutory Changes

Findings:

D1. The VHHA proposed a number of policy changes related to medical prior authorization.

D2. The work group could not reach consensus on which of the VHHA proposals were within the scope of the work group’s charge. Therefore, a subgroup agreed to discuss how best to address the proposals.

D3. Work group members generally agreed in principle that policy proposals directly related to the implementation of ePA for medical services should be considered part of the work group scope and should be discussed as part of the ongoing work group deliberations in 2025.

Recommendations:

D1. Within a scope consistent with federal ePA rulemaking, the work group should be tasked with evaluating and recommending policy proposals that will support the effective and efficient adoption of ePA for medical items and services.

4. Looking Ahead to 2025

The work group may pursue legislation during the 2025 Session of the General Assembly to the extent necessary to implement its recommendations. Under its current charge, it will also continue to monitor and report on any relevant federal or state developments, and provide any feedback to the Secretary of Health and Human Resources in the implementation of the provider undue hardship waiver in § 38.2-3407.15:2 B 17, through its current term concluding with its final annual report on November 1, 2025.

Appendix A. List of ePA Work Group Resources and Stakeholders

Federal Government Resources
Centers for Medicare and Medicaid Services
Office of the National Coordinator for Health IT

Virginia Government Resources
State Corporation Commission
Virginia Department of Health Professions
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 Dental Association
Virginia Hospital and Healthcare Association
Virginia Pharmacists Association

Endnotes

[1] Chapters 474 and 475, (HB 1471 and SB 1261, respectively) Virginia Acts of Assembly – 2023 Session.
[2] NCPDP, "NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA): Fact Sheet," Jan. 2015, NCPDP_ePA_Fact_sheet.doc (live.com). "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 payer-specific web portals."
[3] State Corporation Commission, Report of the Electronic Prior Authorization Work Group, Nov. 1, 2022, at 7.
[4] State Corporation Commission, Report of the Electronic Prior Authorization Work Group, Nov. 1, 2022, at 3.
[5] Chapters 474 and 475, (HB 1471 and SB 1261, respectively) Virginia Acts of Assembly – 2023 Session.
[6] Kaiser Family Foundation, State Health Facts (2022), Health Insurance Coverage of the Total Population | KFF. In addition, employer-based accounts for 53%, with roughly 18% of that private commercial coverage; non-group at 4.7%, and the uninsured at 6.6%.
[7] Subsequent to enactment of the legislation creating the Virginia ePA work group, the House Committee on Commerce and Energy was renamed the Committee on Commerce and Labor, and the House Committee on Health, Welfare, and Institutions was renamed the Committee on Health and Human Services.
[8] "Critical Highlights of the HTI-2 Proposed Rule," https://www.drummondgroup.com/blog/critical-highlights-of-the-hti-2-proposed-rule, Aug. 21, 2024.
[9] "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule," published Aug. 5, 2024)
[10] 89 Fed. Reg. 8761 (Feb. 8, 2024), https://www.federalregister.gov/d/2024-00895/page-8761
[11] 89 Fed. Reg. 8858 (Feb. 8, 2024), https://www.federalregister.gov/d/2024-00895/page-8858, "As discussed in section I.D. of this final rule, we (CMS) exclude drugs from the provisions in this section, meaning any drugs that could be covered by the impacted payers affected by these provisions. Thus, the policies herein do not apply to prescription drugs that may be self-administered, administered by a provider, or that may be dispensed or administered in a pharmacy or hospital, or OTC drugs that may be covered by an impacted payer. We include a definition of drugs for purposes of this exclusion for each impacted payer in the CFR where applicable to provisions for implementation of the Prior Authorization API. For MA organizations, the definition of drugs also includes any products that constitute a Part D drug, as defined by 42 CFR 423.100, and are covered under the Medicare Part D benefit by MA-PDs; this part of the definition specific to MA organizations provides a clear dividing line for MA-PD plans that must comply with this new rule."
[12] 89 Fed. Reg. 8766 (Feb. 8, 2024), https://www.federalregister.gov/d/2024-00895/page-8766.
[13] CMS-0057-P, "Advancing Interoperability and Improving Prior Authorization Processes," 87 Fed. Reg. 76238 (published Dec. 12, 2022).
[14] Managed Care Organization.
[15] Christine Moundas, Gideon Zvi Palte, and Carolyn Lye, "CMS Finalizes New Electronic Prior Authorization Requirements for Payers and Providers," Jan. 23, 2024, CMS Finalizes New Electronic Prior Authorization Requirements for Payers and Providers | Insights | Ropes & Gray LLP (ropesgray.com) (as of Sept. 17, 2024).
[16] "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule," 89 Fed. Reg. 1192 (Jan. 9, 2024), Federal Register :: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.
[17] "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule," 89 Fed. Reg. 8758 (Aug. 5, 2024), Federal Register :: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability).
[18] "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, 89 Fed. Reg. 1192 (Jan. 9, 2024).
[19] "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule," 89 Fed. Reg. 8758 (Aug. 5, 2024).
[20] Statement of Margaret Weiker with the NCPDP at the Electronic Prior Authorization Work Group meeting, Aug. 31, 2023.
[21] Statement from pharmacist John Seymour at the Electronic Prior Authorization Work Group meeting, Aug. 31, 2023.