Q2 2024 State and Federal Regulatory and Legislative Activity Update

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The drug pricing regulatory and legislative landscape continues to evolve rapidly at federal and state levels. Below, we highlight a few of the major changes that have occurred between February 29 through May 23, 2024.

Federal regulatory activity

Commercial business

Notice of Benefit and Payment Parameters (NBPP) final rule

On April 2, 2024, CMS issued the NBPP final rule. CMS finalized the following policies related to prescription drugs:

- Revised the minimum membership standards for Pharmacy & Therapeutics (P&T) committees to include a patient representative. CMS requires the patient representative to:
  - Have relevant experience or participation in patient or community-based organizations
  - Demonstrate the ability to integrate data interpretations with practical patient considerations
  - Have a broad understanding of one or more conditions or diseases, associated treatment options, and research
  - Disclose their financial interests
- Codified its current policy that prescription drugs in excess of those covered by a state's essential health benefit (EHB)-benchmark plan are considered EHBs and would be subject to EHB protections, including the annual limitation on cost-sharing and the restriction on annual and lifetime dollar limits, unless the drug is an additional state-mandated benefit, in which case, it would not be considered an EHB. The final rule does not address the application of this policy to Large Group market health plans and self-insured group health plans. However, in separate sub-regulatory guidance, the U.S. Departments of Health and Human Services (HHS), Labor and Treasury (the Departments) noted that they intend to issue rulemaking that would align this policy across all markets for purposes of the annual limitation on cost sharing.
- Retained the current United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) to classify the prescription drugs required to be covered as EHB. HHS notes they may consider changes to the drug classification system—which could include anti-obesity medications—in future rulemaking.

Prescription drug reporting

On April 30, 2024, the Departments published an updated version of the proposed Reporting Instructions for Prescription Drug Data Collection (RxDC) for the 2023 Plan Year, due by June 1, 2024. The 30-day comment period closed on May 30, 2024 – two days before the RxDC reports are due. Concurrently, the Departments submitted the updated version of the reporting instructions to the Office of Management and Budget (OMB) for review.

General drug update

White House Budget

On March 11, 2024, the White House released the President's Budget for fiscal year (FY) 2025. The President is requesting $130.7 billion for the Department of Health and Human Services, a 1.7 percent increase from FY2023 and $7.2 billion for the U.S. Food and Drug Administration (FDA), a 7.4 percent increase from FY2023.

Among the drug provisions, the President proposes to:

- Expand the number of drugs subject to price negotiation under the Medicare Drug Price Negotiation Program; and,
- Extend the $2,000 Medicare cap on out-of-pocket prescription drug costs and the $35 cost-sharing cap for insulin to the commercial market.

HHS white paper on preventing shortages

On April 2, 2024, HHS released a white paper that describes policy concepts for consideration, including collaboration with the private sector to develop and implement a Manufacturer Resiliency Assessment Program (MRAP) and a Hospital Resilient Supply Program (HRSP) aimed to bring transparency into the market, link purchasing and payment decisions to supply chain resilience practices, and incentivize investments in supply chain resilience and diversification in the supply chain—including domestic manufacturing—at a scale that would drive impactful change in the market.

Congressional Budget Office (CBO) request for research

On April 29, 2024, the CBO released a presentation calling for research on how Medicare's coverage of anti-obesity medication would affect the federal budget as lawmakers consider legislation removing Medicare coverage restrictions.

Federal Trade Commission (FTC) drug patent listing challenges

On April 30, 2024, the FTC sent warning letters to 10 drugmakers, alleging more than 300 improperly listed patents used to delay generic competition. The letters targeted medications for diabetes, weight loss, asthma, and chronic obstructive pulmonary disease.

Reclassification of marijuana proposed rule

On May 16, 2024, the U.S. Drug Enforcement Administration (DEA) issued a proposed rule (with a 60-day comment period) to move marijuana from its current classification as a Schedule I drug to a Schedule III drug, thereby loosening federal DEA restrictions. Rescheduling to Schedule III also means that marijuana would remain subject to applicable provisions of the Federal Food, Drug, and Cosmetic Act.

National Institutes of Health (NIH) Request For Information (RFI) on promoting access

On May 21, 2024, the NIH issued an RFI seeking input on a proposed policy that would require innovators of NIH-owned inventions (including drugs, biologics, vaccines, or devices) to submit an Access Plan outlining steps they intend to take to promote patient access to the licensed product. The Access Plan would address the anticipated patient populations; other products, tools, facilities, or unique resources necessary for the licensed product; and one or more strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability. Comments on the RFI are due on July 22, 2024.

Congressional activity

Senate activity

Drug shortages

On May 3, 2024, the U.S. Senate Finance Committee released a discussion draft to address and mitigate generic drug shortages. The draft would establish a voluntary Medicare Drug Shortage Prevention and Mitigation Program requiring participants to meet minimum standards and requirements to receive Medicare incentive payments. They include:

- Minimum three-year contracts with generic drug manufacturers
- Purchase volume and stable pricing commitments
- Contingency contracts with alternate manufacturers
- Prohibition of exclusive provider contracting requirements
- Transparency standards to address quality control issues, and
- Modifications to the Medicaid Drug Rebate Program to allow for reductions or waivers to the inflation rebate for certain generic drugs in the event of a shortage.

Comments on the draft are due to the Committee on June 2, 2024.

Senate committee hearing on weight loss drug prices

On April 24, 2024, the Senate Health, Education, Labor, and Pensions Committee (HELP) Chairman sent a letter to the Novo Nordisk Chief Executive Officer concerning the list and net prices of Ozempic and Wegovy. The Chairman requested information about the following:

- Costs and volumes of the drugs sold
- Prices paid by government payers
- Revenue Novo Nordisk has made from selling the drugs
- Manner in which prices are determined, and
- Research and development expenditures linked to the drug

On May 16, 2024, the Senate HELP Committee issued a report that found that higher uptake of Wegovy and new weight loss drugs among adults with obesity at current net prices could lead to an unprecedented increase in prescription drug spending. The report also found that the magnitude of savings new weight loss drugs will achieve relative to their price appears to be overstated.

Senate Judiciary Committee hearing on prescription drug competition

On May 21, 2024, the Senate Judiciary Committee titled, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market." The hearing largely focused on curbing abuses of the patent system by drug companies to improve competition between brand drugs and generics and biosimilars.

Senators introduce the electronic prior authorization for Prescription Drugs Act

On May 17, 2024, a group of bipartisan Senators, including U.S. Senators Roger Marshall, M.D. (R-KS), Ben Ray Luján (D-NM), Roger Wicker (R-MS), Sheldon Whitehouse (D-RI), and Joe Manchin (D-WV), introduced legislation that would establish an electronic prior authorization (e-PA) process for commercial plans.

House activity

PBM reform

On May 8 and May 16, 2024, the House Committee on Ways & Means and the House Committee on Energy and Commerce, respectively, advanced legislation extending authorities for telehealth services and other home-based healthcare services in Medicare. Embedded in both pieces of legislation are provisions that would mandate PBMs be compensated only bona fide service fees under Medicare Part D.

State legislative activity

Recently enacted major legislation

Kentucky

On April 15, 2024, the Governor of Kentucky signed SB 188 into law, restricting a PBM from incentivizing, through cost-sharing requirements or other means, the use of a mail-order pharmaceutical distributor or PBM pharmacy affiliate; requires a PBM to provide equal access to network participation to all pharmacies in the geographic area.

The enacted bill also prohibits a PBM or insurer from paying a pharmacy less than $10.64 for filling a prescription; collecting any portion of a co-insurance or co-payment that was paid by a patient to the pharmacy; reimbursing a pharmacy less than the national average acquisition price for a drug; and, reducing payment for pharmacy services through reconciliation process unless the claim was fraudulent or initially overpaid.

The legislation applies all these provisions to self-funded ERISA plans "to the extent permitted by federal law." The Department of Insurance is reviewing existing law and recent court decisions to determine applicability.

Idaho

On April 1, 2024, the Governor of Idaho signed HB 596 into law, which mandates PBMs use pass-through pricing for its clients and pass-through 100 percent of manufacturer rebates. It also prohibits PBMs from having networks that only include affiliates or incentives for using affiliate pharmacies. PBMs may not require or incentivize the use of mail order. They must also pay a "reasonable" dispensing fee to pharmacies to cover costs, which will likely be further defined by regulation. The legislation applies to Medicaid and all Commercial coverage, including self-funded ERISA plans. The new law is effective on January 1, 2025.

Oregon

On March 28, 2024, the Governor of Oregon signed HB 4113 into law, requiring a health plan or PBM to include any third-party payments (e.g., drug manufacturer copay assistance) when calculating an enrollee's overall contribution to any cost-sharing requirements. The provision's applicability is limited to cases where a drug does not have a generic equivalent or has a generic equivalent and the enrollee has obtained prior authorization from the insurer or PBM.

Washington

On March 25, 2024, the Governor signed SB 5213 into law, banning "spread pricing" by prohibiting a PBM from reimbursing a contracted pharmacy less than the contracted price with the client. It also prohibits PBMs from requiring or incentivizing the use of affiliated pharmacies. The bill applies to commercial coverage but excludes union-run plans and only applies to self-funded ERISA plans that opt-in to the provisions.

Introduced legislation

By the numbers (as of May 17, 2024)

45 states have introduced legislation that would affect the provision of pharmacy benefits by restricting certain PBM contracts, restricting rebates, mandating benefits coverage, and imposing requirements on pharmacy reimbursement and networks, among others. Drug pricing policy has been a priority for lawmakers and regulators, and we expect that trend will continue into 2025.

Below is a breakdown of states that introduced bills in 2024 that would impact the provision of pharmacy benefits.

- **Employee Retirement Income Security Act (ERISA)** – 22 states introduced bills that would impose language that holds the potential to apply to ERISA. Those states include Alaska, Alabama, Connecticut, Georgia, Iowa, Indiana, Kansas, Kentucky, Maryland, Missouri, Mississippi, North Carolina, Nebraska, New Jersey, Oklahoma, Oregon, Rhode Island, Utah, Virginia, Vermont, Washington, and Wisconsin.

- **Pharmacy networks** – 23 states introduced bills that include provisions impacting pharmacy network design. Below is a breakdown summary of the pharmacy network provisions introduced:
  - Prohibits reimbursement differentiation on affiliate vs. non-affiliate pharmacies, prohibits the practice of steering, directing a patient to use certain contract pharmacies, or imposing different cost-sharing amounts for the use of preferred pharmacy: Alaska, Arizona, California, Iowa, Idaho, Illinois, Kentucky, Maryland, Minnesota, Missouri, Mississippi, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and Wyoming.
  - Requires any pharmacy to be considered in-network as long as it accepts terms and conditions/any willing pharmacy provisions: Alaska, Arizona, California, Iowa, Kentucky, Missouri, Mississippi, Nebraska, New Jersey, Oregon, South Carolina, Wisconsin, and West Virginia
  - Prohibits Accreditation and Credentialing standards more stringent than federal requirements as determinants for network participation: Alaska, California, Delaware, Idaho, Mississippi, Nebraska, New Jersey, Ohio, and Wisconsin.
- **Mail** – 11 states introduced bills limiting the ability to utilize mail-order pharmacies as part of a pharmacy network, including Alaska, Iowa, Idaho, Kentucky, Mississippi, North Carolina, Nebraska, New Jersey, South Carolina, Washington, and Wisconsin.
- **Copay accumulator or maximizer programs** – 18 states introduced bills banning copay accumulator or maximizer programs including California, Florida, Iowa, Louisiana, Maryland, Minnesota, Missouri, Nebraska, New Hampshire, Ohio, Oregon, Rhode Island, South Carolina, and Tennessee.
- **Copay Caps** – 19 states introduced bills that would impose copay caps: Arizona, California, Connecticut, Georgia, Iowa, Illinois, Maryland, Missouri, Mississippi, Nebraska, New Hampshire, New Jersey, New York, Ohio, Rhode Island, Tennessee, Virginia, Washington, and Wisconsin.

- **Coverage mandates** – 26 states propose coverage mandates (ranging from mandating coverage for PReP/post-exposure prophylaxis to over-the-counter contraceptives to anti-obesity drugs): Arizona, California, Connecticut, Delaware, Hawaii, Iowa, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Nebraska, New Hampshire, New Jersey, New York, Oklahoma, Rhode Island, Tennessee, Virginia, Vermont, Washington, and Wisconsin.
- **Formulary management** – 14 states have introduced bills that include formulary management provisions, including frozen formulary. Those states include Arizona, Florida, Iowa, Idaho, Illinois, Kentucky, Minnesota, Missouri, Mississippi, New Jersey, Ohio, Oklahoma, Rhode Island, and Wisconsin.
- **Pharmacy reimbursement** – 17 states introduced bills related to pharmacy reimbursement. Key provisions of these bills include:
    - Cost benchmark reimbursement mandates, including mandating a pharmacy be paid at NADAC, acquisition cost, or ingredient cost: Alaska, Alabama, Georgia, Iowa, Illinois, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Mississippi, Nebraska, New Jersey, New Mexico, Ohio, Pennsylvania, Rhode Island, and West Virginia.
    - Mandating a specific dispensing fee be paid to the pharmacy for dispensing a drug including Alaska, Alabama, Idaho, Illinois, Kentucky, Maryland, Minnesota, Mississippi, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, and Rhode Island.
- **Spread pricing** – 15 states introduced bills that either prohibit spread (Medicaid and/or commercial market) or require disclosure of spread to either the state or plan sponsor, including Alaska, California, Iowa, Idaho, Illinois, Indiana, Missouri, Mississippi, Orgon, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and West Virginia.

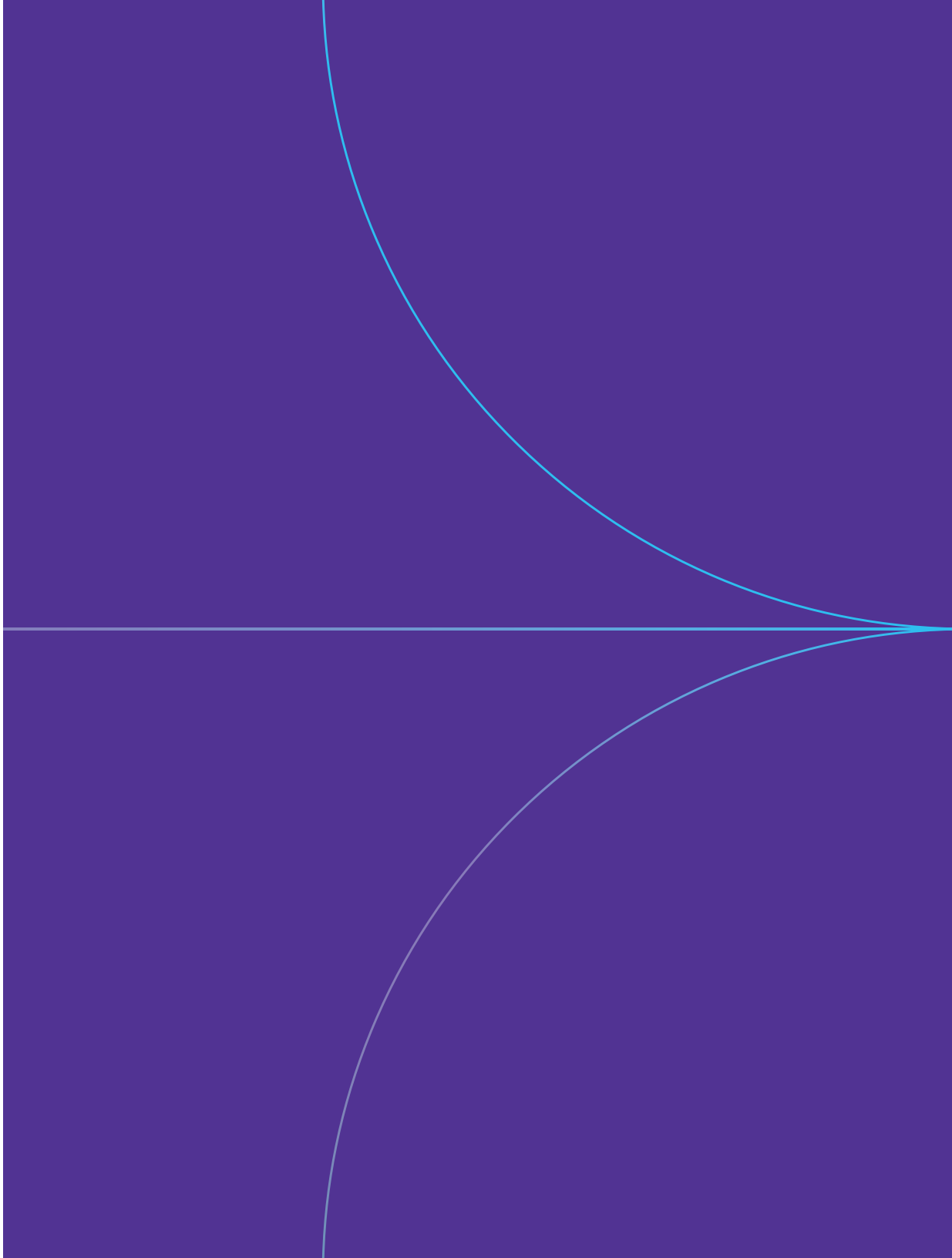
- **Rebates** – Several states introduced bills that would mandate a percentage of drug rebate be applied at the point of sale. Below are the varying types of provisions related to the distribution of negotiated rebates.
    - Mandating that a certain percentage of pharmaceutical manufacturer rebates be distributed to patients at the point of sale and used towards out-of-pocket costs, including Georgia, Louisiana, Maryland, Maine, Michigan, Minnesota, Missouri, New Hampshire, Ohio, and Virginia.
    - Rebate Pass-through model—mandating 100% of all rebates be passed through in some combination to covered individuals at point of sale and/or to the plan sponsor to reduce premiums, including Alabama, California, Kentucky, Idaho, Illinois, Mississippi, New Jersey, New York, Utah, Rhode Island, and West Virginia.
- **PBM compensation/delinking** – 10 states introduced bills that would define what constitutes "PBM compensation," and in some instances, limit PBM's ability to be compensated for its services, including Alabama, California, Idaho, Louisiana, Maine, Minnesota, Mississippi, New Jersey, Rhode Island, and Virginia.
- **White bagging** – 14 states introduced bills restricting white bagging, including Alaska, Colorado, Georgia, Illinois, Louisiana, Maryland, Missouri, Mississippi, Ohio, Rhode Island, Tennessee, Virginia, Washington, and West Virginia.
- **Utilization management** – 37 states have introduced bills to establish new or amend existing step therapy and prior authorization protocols, establish exception and appeals processes, or provide exemption authority for providers with certain approval ratings. These states include Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Nebraska, New Hampshire, New Jersey, New Mexico, New Jersey, New York, Oklahoma, Rhode Island, Tennessee, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming.

Other state activity

- **U.S. Government Accountability Office (GAO) report.** On April 15, 2024, the U.S. GAO released a report describing actions state regulators in Arkansas, California, Louisiana, Maine, and New York have taken to regulate PBMs. After reviewing state laws and interviewing regulators, state health plan associations, and other stakeholders, the GAO found that the selected states have enacted laws establishing fiduciary and other "duty of care" requirements; drug pricing and pharmacy reimbursement requirements; transparency, licensure, and reporting requirements; and pharmacy network and access requirements.
- **National Association of Insurance Commissioners (NAIC).** On May 2, 2024, the NAIC Pharmacy Benefit Manager Regulatory Issues Subgroup modified their charges for 2024, removing the pursuance of a PBM Model Act and instead charging the NAIC with gathering and sharing information, best practices, experience, and data to inform and support dialogue and information-sharing among state insurance regulators on issues related to PBM regulation, such as examinations and contracting, and pharmaceutical drug pricing and transparency.
- ***PCMA v. Mulready.*** On May 10, 2024, Oklahoma filed a petition with the U.S. Supreme Court to review an appeal's court decision in *Pharmaceutical Care Management Association (PCMA) v. Mulready* that ruled in favor of PCMA and found an Oklahoma state law regulating pharmacy benefit managers (PBMs) was preempted by federal regulations, namely the Employee Retirement Income Security Act (ERISA) and Medicare Part D. In its petition, Oklahoma argues that ERISA doesn't apply to PBM operations under any circumstance and that the appeal's court decision conflicts with a previous Supreme Court ruling in *Rutledge v. PCMA*. PCMA's response brief is due by mid-June, and the Supreme Court will consider the petition by or on October 1, 2024.
- **Maryland Prescription Drug Affordability Board (PDAB).** On May 20, 2024, Maryland's PDAB voted to conduct cost review studies for six drugs, including Skyrizi, Trulicity, Ozempic, Jardiance, Farxiga, and Dupixent. The cost review will determine whether the drug has led or will lead to affordability challenges for the state healthcare system or high out-of-pocket costs for patients.

Conclusion

We hope you found this summary of federal and state legislative and regulatory activity helpful. While topics that legislators and regulators are focusing on are constantly evolving, this summary captures many of the issues that are currently in review.



The information in this report is current as of May 23, 2024.

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