



The prescribing authorities for the latest mRNA COVID-19 vaccines at both the federal and New York State levels

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The following description has been provided by ChatGPT 5 in answer to my question:
Which federal and state of NY government offices are responsible for giving Doctors permission to write prescriptions for the latest mRNA COVID-19 vaccines?

Here's how prescribing authority for the latest mRNA COVID-19 vaccines is structured at both the **federal (U.S.)** level and within **New York State**:

Federal (U.S.) Authorities

1. U.S. Food and Drug Administration (FDA)

- **Role:** The FDA reviews, authorizes, or approves vaccines—including updated mRNA COVID-19 vaccines—either via full approval or Emergency Use Authorization (EUA). For example, in August 2024, the FDA approved updated 2024–2025 mRNA vaccines (Comirnaty, Spikevax, etc.) [Gothamist+6U.S. Food and Drug Administration+6Fierce Healthcare+6](#).
- **Prescribing Authority:** A doctor's ability to prescribe a vaccine (or any medication) legally stems from its FDA approval. Doctors may also prescribe vaccines off-label—even after EUA is revoked—unless explicitly restricted [Network for Public Health LawPolitico](#).

2. Centers for Disease Control and Prevention (CDC) / Advisory Committee on Immunization Practices (ACIP)

- **Role:** ACIP, a committee within the CDC, issues recommended guidelines for vaccine use—such as which age groups or risk categories should receive a given vaccine. Once a recommendation is approved by the CDC Director, it becomes the official immunization guidance [Wikipedia+2The New Yorker+2](#).
- **Impact on Prescribing:** Insurers often align coverage with ACIP recommendations, which makes them crucial even though doctors may technically prescribe outside of them—especially following policy shifts that restrict general access [AP NewsPolitico](#).

3. Scope of Practice / Practice of Medicine

- **Role:** The FDA regulates the approval and labeling of drugs and vaccines—not how doctors practice medicine. Once legally approved, physicians have the legal authority to prescribe off-label based on clinical judgment. This authority is governed at the state level [Network for Public Health](#)

[Law.](#)

New York State Authorities

1. New York State Department of Health (NYSDOH)

- **Role:** The NYS Department of Health issues public health guidance on vaccine administration. Particularly during the pandemic, Executive Orders (EOs) allowed non-nurse staff, under supervision and after training, to administer COVID-19 vaccines per FDA/EUA and ACIP guidance [Office of the Professions](#).
- **Current Authority:** While the EO provisions enabled flexibility, the **core authority to prescribe** still rests with licensed prescribers (physicians, NP, etc.) following FDA approval and CDC recommendation.

2. New York Office of the Professions (New York State Education Department)

- **Role:** This office oversees professional licensing and scope of practice. Executive Orders during COVID allowed certain grads and supervised individuals to provide care, but primary prescribing authority remained limited to licensed providers [Office of the Professions](#).

3. Vaccination Training & Reporting

- **Role:** Providers in New York must complete state-specific vaccine training (e.g., via the NYS Vaccine Tracker) and report administered vaccines into the state immunization registry pssny.org.
- **Relation to Prescribing:** These systems regulate administration—not prescription—but form part of the broader regulatory framework in which prescribing and administering take place.

Summary Table

Level	Authority / Function	Role in Prescribing mRNA COVID-19 Vaccines
Federal (FDA)	License or authorize vaccine products	Provides legal basis for prescribing; doctors may also prescribe off-label
Federal (CDC/ACIP)	Issue vaccine use recommendations	Guides official guidance and influences insurance coverage
State (NY)	Licensing, scope-of-practice, training, administration rules	Grants legal authority to prescribe within scope; ensures provider preparedness and reporting

Bottom Line

- **Federally**, the FDA approves or authorizes the vaccines, while the CDC through ACIP issues recommendations.
- **State-level (NY)**, only licensed prescribers can prescribe—and must follow NY licensing regulations. Vaccine administration and provider training/reporting are overseen by NYSDOH and the Office of the Professions.

Let me know if you'd like details about eligible patient groups, how insurance interacts with these prescriptions in NY, or requirements for provider enrollment in immunization programs.

Would you also like to see the latest news on current prescribing policies or insurance coverage?

You said:

yes in particular the latest policy at the federal and state levels for vaccines known as mRNA vaccines directed at COVID-19. In particular the Pfizer and Moderna vaccines.

ChatGPT said:

Here's the latest update as of **September 3, 2025** on the **federal** and **New York State** policies governing the **Pfizer- and Moderna-based (mRNA) COVID-19 vaccines**:

Federal (U.S.) Policy — September 2025

1. FDA Approval & Access Restrictions

- On **August 27, 2025**, the **FDA rescinded all Emergency Use Authorizations (EUAs)** for COVID-19 vaccines, transitioning to more restrictive approval standards. New boosters from Pfizer and Moderna were approved—but **only for individuals aged 65+ or those (any age) with at least one high-risk underlying condition**. Healthy children and adults are no longer broadly eligible. [Reuters+5U.S. Food and Drug Administration+5Vox+5New York Post+3The Verge+3The Guardian+3](#)
- For example, Moderna’s updated vaccine (mRNA-1283, also known as "mNEXSPIKE") received FDA approval on **May 30, 2025**, limited similarly to older adults and high-risk individuals. [Wikipedia](#)

2. Eligibility & Insurance Coverage

- The eligibility scope is narrowed: **only those 65+ or with underlying health conditions** can access the vaccines. Children under five and healthy adults now face access barriers—even though **shared clinical decision-making** may allow off-label prescribing. [Axios+15Axios+15The 19th+15](#)
- Insurance policies remain in flux. Large insurers (e.g., Aetna, Blue Cross Blue Shield, Kaiser) have indicated they may continue covering vaccines for eligible groups, but clarity is ongoing. [Axios+1Wall Street Journal](#)

3. CDC Guidance & Leadership Upheaval

- The **CDC’s Advisory Committee on Immunization Practices (ACIP)** has been **ousted** by Health Secretary Robert F. Kennedy Jr., creating a void in federal vaccine recommendations. [Wikipedia+14Reuters+14Axios+14](#)
- As a result, many states and providers face uncertainty regarding vaccine guidance and eligibility. [ReutersAxiosThe Guardian](#)

4. Labeling & Safety Information

- The FDA recently updated labeling requirements for Pfizer’s **Comirnaty** and Moderna’s **Spikevax** to include new warnings about **myocarditis and pericarditis**, especially among males aged **12–24**. [U.S. Food and Drug Administration](#)

5. Combination with Flu Vaccine

- The FDA is reevaluating its previous stance that allowed **co-administration of COVID-19 and flu vaccines**. Now, simultaneous administration requires separate clinical trial evidence before labeling approval—a shift from prior practice. [The Washington Post](#)

New York State Policy

1. Standing Orders for Vaccine Administration

- The **New York State Department of Health (NYSDOH)** has issued **non-patient-specific standing orders** for both Pfizer and Moderna’s **2024–2025 formula COVID-19 vaccines**, allowing qualified professionals to administer them under pre-approved protocols. [U.S. Food and Drug Administration+13health.ny.gov+13health.ny.gov+13](#)

2. Current Legislative Proposals

- A bill (Assembly **A-4798**, Senate **S-7342**, introduced in early 2025) is under consideration that would **prohibit the administration** of mRNA COVID-19 vaccines **until** the NYSDOH completes a safety study and determines that benefits outweigh risks. The bill remains active and has **not been enacted into law** yet. [nysenate.gov+2nysenate.gov+2](#)

3. Implementation at the Local Level (e.g., NYC)

- According to the **NYC Department of Health**, the updated 2024–2025 vaccine guidelines are in effect:
 - **Ages 65+**: two doses, six months apart.
 - People previously vaccinated: one booster dose, irrespective of brand.
 - **Immunocompromised individuals**: recommended additional doses.
 - **Children younger than 5**: still require multiple doses of updated mRNA vaccines, with dosage depending on history. [nyc.gov+2Wall Street Journal+2](#)

Summary Table: Prescribing Authority for mRNA COVID Vaccines

Level	Authority / Action
Federal (FDA)	Approves vaccines under strict criteria; rescinded EUAs; approval limited to high-risk groups. Warns providers with updated labels; reevaluates co-administration protocols.
Federal (CDC/ACIP)	Advisory guidance currently disrupted due to leadership upheaval; future recommendations uncertain.
State (NY)	NYSDOH issues standing orders for vaccine administration. Legislative proposals could restrict mRNA vaccine use pending safety review. Local guidance (e.g., NYC) aligns with federal high-risk eligibility and dosing protocols.

Bottom Line

- **Federally**, prescribing updated Pfizer and Moderna mRNA COVID-19 vaccines is currently **restricted** to those **65 and older or individuals with underlying high-risk conditions**. The removal of EUAs and ACIP guidance creates uncertainty and access hurdles.
- **In New York**, while NYSDOH supports administration through standing orders, pending legislation could potentially halt mRNA vaccine use pending a safety review—though that legislation is not yet law. Local departments (like NYC’s) continue to follow federal-aligned guidance for now.