



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Drug Formulary Commission
Bureau of Health Care Safety and Quality
99 Chauncy St., 11th Floor
Boston, MA 02111

Dear Chairman Sheehan and Members of the Commission:

Thank you for the opportunity to provide testimony to aid your efforts to prepare a drug formulary of substitutions for Schedule II and III opiates. We appreciate the critical work you are doing to prevent and treat addiction.

As you know, prescription drug abuse has become an epidemic in Massachusetts and throughout the nation. As the largest pharmacy provider in the country and the Commonwealth, CVS Health has a unique perspective on the complexity of the issue. We are committed to being a part of the solution by advancing legislation, promoting technology and creating safer communities.

BACKGROUND

CVS Health provides multiple points of care to patients via our retail, mail, and specialty pharmacies and MinuteClinics. As one of the country's top pharmacy benefits managers ("PBMs"), we also provide access to a network of more than 68,000 pharmacies, including over 7,800 CVS pharmacies, to a broad range of private and public health plan purchasers. CVS Health employs over 12,000 people in Massachusetts. We operate 360 retail pharmacies and 53 MinuteClinics in Massachusetts.

Through our integrated offerings across the spectrum of pharmacy care, we are well positioned to provide greater healthcare access, engage plan members in behaviors that improve their health, and lower overall costs for health plans and their members.

We have been asked to provide commentary on the Commission's efforts to prepare a drug formulary of substitutions for Schedule II or III opiates that you have determined present a heightened level of public health risk due to potential for abuse and misuse, and to address what CVS Health anticipates the impact may have.

We understand that Chapter 258 of the Acts of 2014 directs the Drug Formulary Commission to consider four factors in determining whether a drug should be identified as a therapeutically equivalent substitute, including:

- 1) The efficacy of the potential substitute.
- 2) The effectiveness of the drug's abuse-deterrent properties.
- 3) How the placement of the drug as a substitute may impact the patient and/or pharmacy in terms of access.
- 4) The cost effectiveness of the drug.

QUESTIONS POSED

Please find below comments to the specific questions posed to us related to accessibility:

1) How have you/your organization participated in the process of developing a drug formulary and how did the implementation of the formulary impact your respective field?

We help public and private payors improve outcomes and hold down the cost of drugs by using a broad set of evidence-based clinical programs and proven management tools, including formulary.

Formulary development is increasingly important given the vast number and complexity of products and rising drug prices. We work with our PBM clients to develop a formulary to manage health care costs and improve patient access to care.

Clinical acceptability of the drugs included in the standard formulary is among our primary considerations, enabling us to continue to provide plan members with access to high quality products within all covered classes of drugs.

The work of the CVS/caremark National Pharmacy and Therapeutics (P&T) Committee provides the foundation for the development and management of a formulary. The P&T Committee is an independent external advisory body of experts from a variety of medical specialties, including high-volume specialty physicians, pharmacists and other health care professionals.

Clinical decisions by the CVS/caremark National P&T Committee are based on scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines as well as other sources of appropriate information. The CVS/caremark National P&T Committee also reviews new drug evaluations, new FDA-approved indications and new clinical

line extensions. The formulary selection process also includes a comparison of similar drugs in terms of safety and effectiveness.

Appropriate formularies are critical to ensuring that patients are able to access the safest and most affordable drugs available. It is important to recognize that in creating a formulary, a well-defined process is necessary for physicians and other prescribers who may want to prescribe a non-formulary drug when medically appropriate and indicated. This allows for individual patient needs to be met with a non-formulary drug when demonstrated to be clinically justified by the prescriber.

We also have pharmacists that help patients understand and comply with their prescribed therapies through adherence counseling with new prescriptions (face-to-face at CVS pharmacies), refill reminders and availability of automatic prescription renewals and refills.

Our goal is to provide clients the ability to efficiently and effectively use health care resources, minimize overall medical costs, improve patient access to more affordable care and ultimately provide an improved quality of life.

2) Based on the process that we will undertake to develop our formulary, what obstacles may the Commission encounter?

Developing a formulary presents significant challenges, including:

- **The vast number of drug products currently available.** For example, any alteration to the manufacturer, dosage or packaging must be reflected in the formulary.
- **The health care landscape continues to rapidly evolve.** As a result, tighter controls are essential to help mitigate the effects of trends in drug spending. Promoting the effective use of prescription drugs can help lower overall health care costs and ensure best patient outcomes.
- **Therapeutic interchangeability.** Establishing therapeutic interchangeability between products may pose some challenges to the Commission, as these products use different abuse-deterrent technologies. Additionally, it may be difficult to establish dosage equivalencies, so physicians may be required to provide dosing adjustments, which could delay patients' access to their medications.
- **New products.** Due to the influx of new products, the Commission will need to continuously assess the availability of medications in the market and evolve the strategy to help achieve optimal clinical outcomes with cost-effective prescription choices. Upon

launch, a timely review of a new drug and its therapeutically equivalent substitute will be necessary.

3) What pertinent data / data sources should the Commission review as part of its deliberations?

The committee may want to consider some or all of the following information:

- Medical and clinical literature, including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information, including safety data;
- Relevant information on use of medications by patients and their experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data; and
- Health care provider recommendations
- Instances when multiple therapeutically equivalent substitutable drugs are available, allowing plans to select a preferred formulary product and reduce overall costs through utilization management tools.

4) How will the placement of a drug as a substitute impact the patient and/or pharmacy in terms of access and pain management?

Depending on how this program is implemented, there may be some impact to the patient and/or pharmacy in terms of access and pain management. Due to the pharmacy laws for dispensing of opiates, the pharmacist may need to contact the physician for new prescription for the therapeutically equivalent substitutable drug which could result in delayed pain management for the patient.

a. How do you / your organization monitor success of the drug formulary / patient outcomes?

A formulary is one component of health care management. It enhances other existing medication management practices designed to optimize patient care, including step therapy, quantity limits, and utilization management techniques.

We use a variety of tools, such as drug utilization review and disease management to encourage the best clinical outcomes for patients.

Ongoing monitoring, reporting and analysis of utilization trends and compliance with the preferred formulary products is conducted to ensure drug selection is consistent with optimum therapeutic protocols that align with current guidelines and recognized best practices.

CONCLUSION

CVS Health appreciates the opportunity to provide testimony today. We look forward to working with you to address the opioid epidemic in Massachusetts. CVS Health is committed to creating safer communities by combating prescription drug abuse.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Ayotte", with a stylized flourish at the end.

Michael Ayotte, R.Ph.
Head of State and Local Government Affairs