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HEALTH PLANS

October 13, 2015

Eric Sheehan, J.D., Chair, Massachusetts Opioid Drug Formulary Commission
Interim Director, Bureau of Health Care Safety and Quality
Massachusetts Department of Public Health
250 Washington Street
Boston, MA 02108

Dear Chairman Sheehan:

On behalf of the Massachusetts Association of Health Plans (MAHP), which represents 17 health plans that provide coverage to approximately 2.6 million Massachusetts residents, I am writing to thank you for the opportunity to testify at the Commission's recent informational session.

MAHP and its member health plans recognize the impact that opioid addiction is having on Massachusetts families. Our members are committed to ensuring that residents get the treatment they need and have deployed various strategies to help combat this epidemic. As the Commission continues its work to prepare a list of appropriate abuse deterrent drugs, we appreciate the opportunity to offer our members' perspectives on issues the Commission should consider.

MAHP member health plans have all implemented initiatives to ensure appropriate prescribing practices. This includes limits to the number of pills prescribed to help control access to both long- and short-acting opioids. Additionally, many MAHP member health plans have implemented so-called pharmacy "lock-in" programs that, following identification by the health plan of a member that may be seeking to fill prescriptions by multiple providers at multiple pharmacies, lock the member into a single pharmacy for filling such prescriptions. Some plans also have locked members into one prescriber for the writing of prescriptions as a way to eliminate "doctor shopping" and to alleviate multiple prescribers issuing multiple prescriptions to the same patient.

Our member health plans also have implemented prior authorization protocols for select opiates. This is intended to ensure that powerful narcotics are appropriately prescribed and that there has been a discussion with the prescribing provider to weigh the benefits and risks. Finally, health plans have developed pharmacy monitoring programs in which plans analyze pharmacy claims to monitor utilization of controlled substances. This allows plans to identify individuals who are high utilizers of controlled substances, individuals who use multiple providers and pharmacies, and any prescribers or pharmacies that may be engaged in fraudulent activity.

As we noted in our comments, health plans utilize pharmacy and therapeutics committees (P&T committees) to develop their drug formulary. Their P&T committees, typically composed of physicians from various medical specialties, review the medications in all therapeutic categories based on safety, effectiveness, and cost, and select the most cost-effective drugs in each class. Due to the multiplicity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised listing, and P&T committees meet regularly to review newly released drugs to keep their formularies current.

As part of their review, health plans' P&T committees evaluate medications after Food and Drug Administration (FDA) approval and often consider some or all of the following elements in deciding which drugs to include on their formulary:

- 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 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 (not all P&T committees review drug specific economic data); and
- Health care provider recommendations

Health plans' P&T committees compare medications by therapeutic classifications. When two or more medications produce similar effectiveness and safety results in patients, then elements such as cost, supplier services, ease of delivery or other unique properties of the agents may be considered when determining which agent to include on the formulary. If two or more medications are determined to be clinically equivalent, then business elements will determine formulary inclusion or exclusion. The overall goal is to develop a list of the safest, most effective medications that will produce the desired goals of therapy at the most reasonable cost to the health care system.

It is important that as the Formulary Commission develops its list of substitutions for Schedule II or Schedule III opiates, it provides for flexibility to respond to changes in the marketplace. For example, FDA abuse deterrent approval only addresses the veracity of manufacturer claims relative to the abuse deterrent properties of the drug. It does not address interchangeability of these drugs with any non-abuse deterrent alternative, which requires careful consideration of several important factors. Additionally, there are roughly a dozen products in the pipeline trying to gain abuse deterrent FDA status. This will impact the short acting products as well as adding more options to the long acting products. Whatever strategy the Commission develops needs to be flexible enough for the changing marketplace. Otherwise, it may limit options while increasing costs and may not reduce opioid abuse.

As we noted during our October 1 comments, there are a number of challenges that the Commission should consider, chief among them is that there is only a small range of abuse deterrent drugs. With a limited number of abuse deterrent drugs, there will not always be the ability to match dose for dose or even drug to drug for an abuse deterrent with a non-abuse deterrent drugs. For example, drugs that are chemically equivalent and available in the same dosage often have different extended or continuous release mechanisms. A prescribing physician may see advantages to a particular non-abuse deterrent opioid's release mechanism, and the otherwise equivalent abuse deterrent formulation may not be available with the appropriate release mechanism. Similarly, there exists today a generic, non-abuse deterrent version of morphine sulfate in a 10 mg pill, but the lowest dose of the chemically equivalent abuse deterrent alternative is 20 mg. Because the doses don't always match up, there could be the unintended consequence that an individual receive twice the dosage prescribed by the physician because an abuse deterrent opioid is required.

Further, with so few available opioids approved for abuse deterrent labeling, widespread moves toward these drugs may lead to supply shortages until the FDA approves more and, because many of the abuse deterrent drugs are brand name drugs, limiting individuals to just these options would undermine the state's Generic Substitution Law. For patients on chronic narcotics which are being used appropriately, limiting coverage to FDA indication could have the unintended consequence of individuals who max out on dose but not on the pain control because of long-term tolerance.

Finally, as noted above, FDA abuse deterrent approval only addresses the veracity of manufacturer claims relative to the abuse deterrent properties of the drug. As several speakers noted at the informational hearing, there is a perception that abuse deterrent drugs are somehow safer. However, they are still as dangerous as non-abuse deterrent opioids and there has not been any clinical data to indicate that abuse deterrent drugs are any safer or more cost effective and whether they will actually reduce opioid addiction.

We thank you for the opportunity to offer our comments to the Commission. We remain committed to working collaboratively on ways to help combat the opioid crisis and are available to assist the Commission as it conducts its review. If you, your staff or members of the Commission have any questions or require any additional information, please do not hesitate to contact me.

Sincerely,

Neil Minkoff, MD
Medical Director
Massachusetts Association of Health Plans