Health Insurance Reform Commission

Meeting Summary

November 7, 2016

The Health Insurance Reform Commission (HIRC) held its third meeting of the 2016 interim on November 7, 2016. The following members attended the meeting: Delegate Kathy J. Byron (Chair), Delegate Eileen Filler-Corn, Delegate David E. Yancey, Delegate R. Lee Ware, Senator Frank W. Wagner, Senator Rosalyn R. Dance, and Jacqueline K. Cunningham, Commissioner of Insurance.

Abuse Deterrent Formulations (ADFs) of Opioids - HJ 45

Bea Gonzalez, representing the Capital Results consulting firm, introduced Shruti Kulkarni, Esq., Policy Director of the Center for Lawful Access and Abuse Deterrence (CLAAD). Ms. Gonzalez asked that the HIRC recommend mandating access to ADFs when doctors determine that ADFs are preferred for the patient.

Ms. Kulkarni explained that CLAAD is a not-for-profit organization that works to reduce prescription drug fraud, diversion, misuse, and abuse and advocates for consumer access to quality health care. Efforts encouraged by CLAAD to address the opioid epidemic include prescriber education, safer storage of medications, and treatment for those who abuse or misuse opioids.

The FDA has encouraged the development and use of ADFs. To get an "abuse-deterrent" label from the FDA, the drug must go through rigorous studies to demonstrate that the product reduces known or expected routes of abuse. Some drugs have incorporated ADF features but have not sought the "abuse-deterrent" labeling from the FDA.

Ms. Kulkarni testified that insurers impede access to ADFs by imposing cost/benefit-related restrictions. For example, many insurers use a "fail first" policy that means a patient would have to fail on methadone or a similar generic drug before having access to ADFs even though methadone is many times more likely to cause an overdose death.

ADFs are designed to make unintended overdoses less likely. One method used by ADFs to decrease the risk of overdose is preventing altered routes of administration. Individuals who use altered routes of administration are at an increased risk of overdose. ADFs can also prevent accidental misuse. For example, if an individual crushed an opioid to make it easier to digest, the active ingredient would release all at once, which could result in an accidental overdose. ADFs can also make medications more difficult to manipulate or can increase their unpleasant side effects when manipulated, which could result in lower black market demand.

Arguments against mandating access to ADFs have been that ADFs do not prevent euphoria or addiction, they cost more because there are no generics available, and the health benefits of ADFs are difficult to isolate. Ms. Kulkarni explained that the impact on public health can only be realized once there is increased use of ADFs. Additionally, ADFs are priced on par with other brand name medications. She stated that even an incremental reduction in abuse can have a significant public health impact, considering the widespread nature of the opioid epidemic.

Ms. Kulkarni concluded by emphasizing that CLAAD urges the HIRC to recommend legislation that ensures access to ADFs when deemed necessary by a doctor rather than allow insurers to use a "fail-first" process that could lead to overdose or death.

Doug Gray, Executive Director of the Virginia Association of Health Plans, also spoke on this issue. He testified that the opioid epidemic is a substantial problem in Virginia and nationwide, with just the tip of the iceberg showing. Opioid abuse is a particularly difficult public health issue because opioids are so prevalent in society, but any efforts focused on limiting access to opioids may drive people to heroin use.

Mr. Gray explained that ADFs that are used as directed are still addictive. These formulations may be tamper resistant, but they do not stop abuse. Therefore, insurers do not favor ADFs because of their higher cost and the fact that they can still be abused and are still addictive. Other efforts such as the prescription monitoring system are more effective in addressing this issue. Coverage of ADFs will not be productive until the prescribing and treatment sides are under control first.

In response to a question from Delegate Ware about why mandating coverage of ADFs would help solve the opioid abuse epidemic, Mr. Gray emphasized that providing coverage for ADFs would not stop people from becoming addicted to opioids or from feeling euphoric effects from the drugs. Ms. Kulkarni added that while the ADFs do not prevent addiction, mandating access would allow a prescriber who finds that an ADF would be beneficial to his patient to prescribe that medication. Such patients might include those with teenage children in the house or elderly patients who have an increased likelihood of unintended misuse. Mandating access would also aid development of future generation drugs that avoid addictive properties.

Senator Wagner inquired about the success rates of treatment and alternative pain treatment drugs available. Mr. Gray did not have information available about the success rates of treatment but pointed out that people typically end up in jail rather than in treatment. He suggested that treatment in jail could be a productive way to address the problem. The Centers for Disease Control and Prevention (CDC) has a new standard for prescribing that emphasizes non-opioid medications and therapies over opioid medications. The CDC also recommends short-term prescriptions rather than using opioids as a long-term solution. Ms. Gonzalez responded that only a physician knows the right form of treatment for his patient and, considering the high stakes involved with addiction, he should have the option of prescribing an ADF if that is what he deems necessary. The costs are not as astronomically high as presented, and this effort would not mandate use by everyone; instead, mandating coverage would provide access for those who need it. "Fail first" policies put patients in a very risky position.

In response to a question from the Chair on the benefits of ADFs, Ms. Kulkarni explained that abuse deterrent qualities such as including acetaminophen, which causes irritation when snorted, make the drug more difficult and less enjoyable to abuse. Additionally, these abuse deterrent factors could lead to less black market demand for the drugs.

Proton Radiation Therapy - HB 978 and SB 639

Bill Thomas, Associate Vice President of Governmental Relations at Hampton University, and Dr. Vahagn Nazaryan, Executive Director of the Hampton University Proton Radiation Institute, began the discussion on proton radiation therapy. Mr. Thomas explained that the Proton Radiation Institute is asking the HIRC to allow patients and prescribers to be able to make

choices and have access to this therapy, which is available at Hampton University and few other places in the country. Proton radiation therapy is Medicare approved and FDA approved. The facility at Hampton University has saved over 2,000 lives, and it has the largest capacity in the country for serving veterans. Other universities, such as Stanford University, are beginning to invest in proton radiation therapy. Additionally, the scale of the costs is coming down. Dr. Nazaryan testified that insurance companies generally do not cover proton radiation therapy even when they cover other radiation therapies, and he opined that insurers need to give options to their patients and provide coverage for this therapy.

Mr. Gray from the Virginia Association of Health Plans testified that proton radiation therapy is not covered by most insurers because there is no evidence that it is better than other radiation therapies and it is more expensive. Plans choose to cover less expensive therapies that are just as effective. Mr. Gray stated that this technology is not being evaluated differently than other technology but that evaluations show that it is not cost effective.

Delegate Ware asked Mr. Gray to respond to a review from a medical authority that indicated that proton radiation therapy is particularly effective in treating certain complex cases. In response, Mr. Gray indicated that proton radiation therapy may be covered in some specific cases. Mr. Thomas responded that the efficacy of this treatment has been accepted elsewhere, as evidenced by the fact that other states are expanding this treatment and that the Department of Veterans Affairs has accepted it. In response to a question from Delegate Yancey, Dr. Nazaryan testified that proton radiation therapy is able to treat certain ailments that result from exposure to Agent Orange.

Discussion

The Chair asked Mr. Gray what danger might exist in having ADFs on the formulary when there are already such substantial differences in pricing on the formulary. Mr. Gray explained that cost share is limited because it is already being used to cover other extremely high priced drugs, such as the medication necessary to treat Hepatitis C. Allowing products to compete rather than mandating coverage enables health plans to manage costs. Because there are no generics for the ADFs, they cannot compete with other opioid medications.

In regard to the proton radiation therapy issue, Commissioner Cunningham pointed out that both internal and external appeal processes currently exist for the patient if the insurer will not cover a specific type of treatment. In response to follow-up questions, staff explained that the proposed legislation would not mandate coverage of proton radiation therapy but it would prohibit insurers from holding proton radiation therapy to a higher level of clinical evidence for benefit coverage decisions than other types of radiation therapy treatment.

The HIRC made no recommendation on the proton radiation therapy bills and decided to continue reviewing this issue and invite others to learn more about proton radiation therapy.

The HIRC made no recommendation on the abuse deterrent opioid formulation resolution but indicated that the HIRC will continue to review this issue independently.

Conclusion

Before adjourning the meeting, the Chair announced that the final HIRC meeting will be held on January 5, 2017, at 1 p.m., at which time the HIRC will be discussing COPN and Direct Primary Care.