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House Bill 2113

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Chairman Godshall, Chairman Caltagirone and members of the House Consumer Affairs Committee, thank you for the opportunity to engage in the public policy discussions surrounding House Bill 2113.

Highmark Inc. (Highmark) is the insurance arm of Highmark Health, an integrated delivery and financing system providing commercial health insurance products in Pennsylvania, West Virginia, and Delaware; delivering an array of other products through various diversified business entities, and providing direct health care services through the Allegheny Health Network. The comments and recommendations presented to the committee today represent the view of Highmark which provides health insurance coverage to over four million lives in Pennsylvania.

Background

Health insurance market dynamics and limitations of state mandates

Before addressing the specifics of the legislation, it is important to understand the limitations of state health insurance mandate legislation. The Pennsylvania health insurance market is diverse, competitive, and complex. To generalize, the health insurance market can be broken down into the following segments:

- Individual
- Fully-insured small group—employers with no more than 50 employees
- Fully-insured large group—employers with 51 or more employees
- Self-insured group employers—an employer of any size that assumes the insurance risk, i.e. establishes a fund to pay claims, and uses a third party administrator to perform the administrative functions of delivering health insurance (e.g. sending claims payments, establishing a network of providers)
- Government business—Medicare (both Medicare Advantage and supplemental policies), Medicaid, CHIP

This breakdown is relevant because health insurance mandates, such as House Bill 2113 can only impact the fully insured market. The self-insured and Medicare markets are governed by federal law. State legislation *may* have an impact on joint state and federal programs such as CHIP and Medicaid, but several factors need to be evaluated to determine the full scope ad impact of state law.

Description of pharmacy and medical policy updates

The pharmaceutical world changes on a daily basis—new medications are introduced into the marketplace frequently, existing medications can receive approval for new and expanded indications, and existing medications can be reformulated or altered. To keep pace with the ever evolving pharmaceutical world, Highmark has established a comparative effectiveness research (CER) medicine evaluation program to provide uniformity and transparency in the evaluation of pharmaceuticals and new technologies. Highmark uses evidence-based medicine (EBM) principles to assess new drugs and biologics based on information and input from several sources. When a new molecular entity is approved by the Food and Drug Administration (FDA), Highmark completes a clinical review of the therapeutic class to which the new entity

belongs. The clinical review consists of consolidating information from national and international data. In addition, research and evaluation of medications often continue post FDA approval requiring constant evaluation and monitoring of clinical evidence. Highmark clinical team members review ever emerging clinical evidence and research. In addition, expert opinion from leading clinicians is incorporated into the therapeutic class review. Direct and indirect comparisons to alternative therapies are evaluated to determine an overall value conclusion for the product under review and its net health benefit for treatment. By integrating key aspects of evidence based medicine (EBM) and adopting Institute for Clinical and Economic Review (ICER) tools, Highmark has built a solid foundation for assessing the rigor, quality, and relevance of pharmaceutical scientific research and synthesizing clear value conclusions to make well-informed formulary and utilization management decisions.

With the CER medicine evaluation program as its foundation, Highmark's Pharmacy and Therapeutics (P&T) Committee meets on a quarterly cadence to review and update the prescription drug formularies and pharmaceutical management policies and procedures. This is necessary to maintain pace with clinical and scientific evaluation and research. Consequently, decisions are sometimes made to change formulary status of a medication or to require new utilization management criteria to manage the use of a medication. When such decisions are made and approved by the Pharmacy and Therapeutics Committee, both members and prescribing physicians receive notification of the changes, allowing a time period which meets regulatory requirements. This notification allows ample time for the member to communicate with his/her physician to determine what alternative therapies meets the best needs of the member. If a medication now requires that certain utilization management criteria be met, both members and physicians always have the right to submit a prior authorization request to coverage of said medication while showing the medical necessity of the medication. Changes are not made indiscriminately, but for documented clinical reasons based on providing the best patient care. Also, changes made to pharmacy formularies are not tied to a particular contract year; they take place based on the emerging clinical evidence.

Similarly, medical policy has historically been reviewed on an annual (not by policy contract year, but by calendar year) and any changes would be made based upon the available research and evidence. Given the ever accelerating evolution of medical science and research, Highmark now accommodates medical policy review and change throughout the year. In fact, when providers or members raise a question or concern about a medical policy, the medical policy team may review a policy in order to evaluate new evidence and update policy to assure members are receiving appropriate care. These changes could be adding, amending or limiting coverage based on medical evidence, not based on contract year.

Highmark's approach to medical and pharmaceutical policy must maintain the flexibility to adapt and evolve based on the emerging science and not be anchored to a specific time frame that prohibits change.

In terms of House Bill 2113 specifically, Highmark's comments cover two general areas: Questions and Observations.

Questions

In reviewing this legislation, Highmark has identified several questions that are critical to providing a full assessment/analysis for the committee:

- Does the legislation intend to restrict changes to all benefits (e.g. medical, behavioral, dental, vision and pharmaceutical) or just pharmaceutical?
- The legislation would prohibit a health insurance policy from raising the copayment, coinsurance, or deductible. We presume that the legislation intends to prevent changes in the coinsurance (e.g. changing from 10% to 20%) and deductible (changing from $1,000 to $2,500) amount and not the exact out of pocket cost the customer pays at the point of service? Deductible and coinsurance amounts that a consumer may pay at the point of sale could change because these cost sharing tools are based on the price of the service. For example, if a person has a policy with a 10% coinsurance and fills a prescription in January that costs $100, the out of pocket cost would be $10. The same member returns in February to fill the same prescription, but the actual cost of the medicine has increased to $200, the out of pocket cost would be $20. In this situation, the coinsurance did not change, but the cost of the medication did change. The legislation would have to place a price freeze on the cost of services to avoid a change in out of pocket costs for coinsurance and deductible obligations.
- The legislation exempts benefits that the FDA has called "into question the clinical safety of the benefit" or the manufacturer of a prescription or the FDA issues a notice of discontinuance or potential discontinuance of the drug. Both of these exemptions are only applicable to pharmaceutical benefits and perhaps certain medical technologies or equipment—how would the bill allow for safety related changes or clinical evidence studies of medical procedures? Behavioral health procedures?
- Are there specific medications or procedures or benefits that have prompted this legislation?
- Does the legislation intend to place these restrictions on Pennsylvania's public programs such as Medicaid and PACE?

Observations

Policy oriented

Without having a full picture of the problem or challenge that House Bill 2113 seeks to resolve, Highmark offers the following observations. It appears that House Bill 2113 would impede a health insurer's ability to adapt medical and pharmaceutical policy to reflect the current scientific data. Rather, the legislation would require that such medical and pharmaceutical adaptations wait for a point in time in order to change. This standard places the customers (patient's) access to the most current medical or pharmaceutical treatment on an artificial timeline.

Further, the House Bill 2113 restrictions could result in members/patients experiencing greater out of pocket costs and greater overall medical costs. As a case example, a Highmark member was unable to fill a prescription for Metformin ER 1000mg (Generic Fortamet) at a local pharmacy. The pharmacist contacted member and prescriber to open a dialogue about options for the patient. The member switched to the lower cost alternative (Generic Glucophage), saving the member $1,700.00 year in out of pocket (or cost sharing) costs and reduced the overall costs associated with the prescription by $9,564.04 year

Technical

Section 15 (ii) of the bill would subject a health insurance policy to the "Unfair Trade Practices and Consumer Protection Law." Highmark notes that health insurance policies are governed by existing Pennsylvania Insurance laws, such as the Unfair Insurance Practices Act, which House Bill 2113 proposes to amend. Subjecting a health insurance policy to a different state law that has additional enforcement provisions is unnecessary, repetitive, and provides no additional value to our customers.

Section 15 (iv) of the bill would clarify that House Bill 2113 would not inhibit the applicability of the Generic Equivalent Drug Law (GEDL). The GEDL falls under the purview of the Pennsylvania Department of Health, requiring pharmacists to substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or prescriber. The GEDL has no impact on health insurance policies and its inclusion in House Bill 2113 does not appear to permit an action that otherwise would be permitted absent the inclusion of this language.

Section 15 (v) of the bill would clarify that the bill does not prohibit a health insurer from adding benefits to a health care policy during the term of the policy. This section should also include language that would permit the health insurance policy to include any applicable copayments, coinsurance or deductible with the additional benefit.

Conclusion

In a simple description, a health insurance policy is a contract between the health insurer and the customer—sometimes the customer is an individual or an employer providing health insurance on behalf of its employees. Health insurance policies are thoroughly regulated by the Pennsylvania Insurance Department and the federal Department of Health and Human Services, among many other entities. Multiple avenues are available to members/patients and providers to appeal benefit decisions, including formulary changes. This process provides the necessary regulatory protections for patients while allowing health insurance policy coverage to adapt to clinical and scientific advances, research (including evaluation and re-evaluation of existing medications and procedures) to best serve the patient.