INSURANCE ADMINISTRATION

Maryland Insurance Administration Pharmaceutical Services Workgroup Report

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January 10, 2018

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I. Legislative History & MIA Workgroup

During the 2017 legislative session, the Maryland Insurance Administration (MIA) convened an informal workgroup ("Workgroup") at the request of the House of Delegates Health and Government Operations Committee Chairwoman Shane Pendergrass to explore certain pharmaceutical service-related issues and concerns. The concerns, which had been raised by stakeholders during the 2017 General Assembly session, involved the following three bills:

- HB 1103, concerning a pharmacist's authority to decline to dispense a prescription or provide a pharmacy service if reimbursement will be less than acquisition cost;
- HB 1117, concerning a pharmacist or pharmacy's authority to dispense "specialty drugs;" and
- HB 1162, concerning fees charged to pharmacies by a pharmacy benefit manager (PBM) or purchasers which are not enumerated at the time the claim is processed.

The stated goal of the Workgroup was to find common ground among the stakeholders and, in particular, among the independent pharmacists, insurance carriers, and PBMs, in order to resolve the concerns raised during the legislative committee hearings. Despite its best efforts, the Workgroup was unable to find common ground among these stakeholders.

Five public meetings were held by the Workgroup between July and November 2017. The first two were held in Annapolis and the final three were held at the MIA's office in Baltimore. Meeting dates were as follows: July 26, August 11, September 25, October 23 and November 13, 2017. The meetings were regularly attended by independent pharmacists, representatives of insurance carriers, PBMs, and the Maryland Pharmacists Association and the Pharmaceutical Care Management Association. No consumer groups or consumer advocates were in regular attendance at the meetings.

The Workgroup explored topics within each bill independently, but there was considerable crossover in discussions of the various issues. In addition to presenting the issues as stated by the stakeholders and summaries of the discussions, this report sets forth potential solutions for consideration by the General Assembly.

II. Issues Discussed

A. HB 1103: Maximum Allowable Cost (MAC) Pricing (2nd, 4th and 5th Meetings)

- Is § 15-1628.1 of the Insurance Article[1] working as intended?
    - Does this law intend for pharmacists to be required to dispense a prescription at a loss?
- Are parties to the appeal complying with the processes in § 15-1628.1(f), specifically (f)

[1] Unless otherwise noted, all statutory references are to the Insurance Article, Annotated Code of Maryland.

(4) and (f) (5)?
    - How, if at all, should the language be amended to require the actual purchasing source to be provided as part of the claim denial? Should the law specify that the National Drug Code ("NDC") included must be from a wholesaler that sells to pharmacies in Maryland?
- If an appealed claim is upheld, should the pharmacy be required to resubmit that claim for re-adjudication?
- Why should a claim handled by a PBM not be adjudicated and paid at an amount no lower than what the PBM would pay its own pharmacies or affiliates?
- National Average Drug Acquisition Cost ("NADAC")
    - How does NADAC reimbursement amount compare to the Maximum Allowable Cost ("MAC") list reimbursement? If reimbursements are higher, in aggregate, from a MAC list, are NADAC prices useful? If so, how?

B. HB 1117: Specialty Drugs (1st, 3rd, 4th and 5th meetings)

- The definition of "specialty drug" as found in § 15-847(a)(5):
    - Is "complex or chronic medical condition" too broad?
    - Should the $600 cost for a 30-day supply be raised to a higher amount?
        - $1,000, $1,500, or $2,500?
    - If the $600 threshold is increased, what impact, if any, would this have on the $150 copay cap [§15-847(c)] for specialty drugs and consumer spending (i.e. premiums and cost-sharing)? Are there concerns from carriers/PBMs about care management if certain drugs were to no longer be classified as specialty?
    - What constitutes "typically stocked" per § 15-847(a) (5) (iii)? Who would have burden of proof?
    - What impact if an exception were added for drugs which are taken orally or are self-injectable?
    - What if the definition excluded medications which are not treated as specialty by Medicare or Medicaid?
- Are licensed pharmacies capable of being designated as "specialty" pharmacies for the purposes of dispensing specialty drugs?
    - How do pharmacies apply for designation?
- Do current carrier performance standards prevent pharmacies from being able to become a participating specialty pharmacy?
    - Accreditation Standards: URAC, Joint Commission: Accreditation, Health Care, Certification ("JCAHO"), Accreditation Commission for Health Care ("ACHC"), and Center for Pharmacy Practice Accreditation ("CPPA")
    - What are the negatives/perceived issues with non-URAC accreditations? What are the *substantive* differences between various accreditation standards?
    - Requirements from carriers to have two of these accreditations
    - Other requirements to be in the network besides accreditation (care management, disease coordination, etc.)
- Drugs which independent pharmacists believe should not be designated as "specialty"
    - Examples: Insulin; drugs for HIV, rheumatoid arthritis, high cholesterol

- Drugs which are taken orally or via a self-injection and whose only additional requirements are refrigeration and adherence counseling; 77 such drugs on the CareFirst formulary out of more than 400 specialty drugs on the formulary
- Variances in lists of specialty drugs by carrier/insurance plan

C. HB 1162: Fees Not Specified at Time of Claim (5th Meeting)

- What right does a plan, carrier, or PBM have to charge fees not enumerated at time claim is processed?
- Established and clarified the differences between a "claw back" and a Direct and Indirect Remuneration (DIR) fee
- DIR fees are currently in Medicare Part D; is there any language, of any kind, about such fees in current contracts which MIA has jurisdiction over?
- "Carrot" incentives vs. "Stick" disincentives/penalties

III. Summary of Maximum Allowable Cost ("MAC") Pricing Discussions

A. MAC Pricing and Appeals

1. Is § 15-1628.1 of the Insurance Article working as intended? Does this law intend for pharmacists to be required to dispense a prescription at a loss?

- Carriers and PBMs stated the intent of the law is not to guarantee a profit by the pharmacy on every prescription dispensed. Pharmacies can be expected to make money on some drugs dispensed and lose on some others based on the pharmacy's acquisition costs and insurance reimbursement amounts. It is a simple inventory cost versus customer payment model like any other business. There is no profit guarantee in any business.
- Regarding the MAC list claims pricing and appeals, independent pharmacists contend that things have not improved since the enactment of the new law in 2015. If a drug is in stock, participating pharmacies are contractually obligated to dispense the drug to a plan member. To avoid taking a loss on certain drugs, the pharmacies will not stock them, forcing patients to seek certain drugs elsewhere. The independent pharmacists also state they cannot negotiate their contracts with PBMs or carriers because the participating provider contracts are contracts of adhesion.

This law has been in effect since January 1, 2015, and the MIA has received very few complaints since that time regarding MAC pricing. Therefore, there is not enough data upon which to conclude that the law is working as intended. The MIA did receive a number of MAC reimbursement related complaints following the conclusion of the Workgroup meetings and these complaints are currently under investigation.

The law, however, was not intended to require pharmacies to dispense prescriptions at a loss, nor was it intended to guarantee pharmacies a profit. Dispensing drugs, if they are in stock,

is a contractual obligation for the pharmacy if it wishes to continue to be a part of the carrier's or PBM's network.

2. Are parties to the appeal complying with the processes in § 15-1628.1(f), specifically (f)(4) and (f)(5)?

- Independent pharmacists asserted that PBMs frequently do not comply with the appeals processes in this statute. Alleged violations discussed by the workgroup included:
    - Failure to provide an NDC [§15-1628.1(f)(4)(ii)] and instead simply stating the drug is "cheaper elsewhere."
    - Upholding a pharmacy's appeal and making an upward adjustment to the MAC price, but not making the adjustment retroactive, preventing the pharmacy from reversing and rebilling the claim, possibly in violation of § 15-1628.1(f)(5)(ii)
    - Upholding an appeal and making an upward adjustment to the MAC price, only to decrease the MAC price again in subsequent claims.
- Representatives of the PBMs did not expressly contest these alleged violations, although they did state their claims adjudication systems are automated and sometimes there can be mistakes in the data the system uses to make judgments. PBMs further stated their employees do not go back through the data and actively change it or make arbitrary decisions to deny MAC appeals.

To support claims of a PBM's failure to provide an NDC on appeal, one independent pharmacist provided the MIA with documentation from four appeals on prescriptions filled between November 2016 and January 2017 where the PBM's response is simply, "Please check with your wholesaler for availability." The pharmacist further provided data on 559 appeals the pharmacy filled between May 2017 and November 2017. Of these appeals, only seven appear to have resulted in an increase in the MAC price, with only one of these increases effective retroactive to the date the prescription was filled. The remaining six MAC increases were effective anywhere from seven days to more than a month after the date the prescription was filled. Of those appeals which were denied, 180 did provide an alternate NDC as required by §15-1628.1(f)(4)(ii) of the Insurance Article, while 89 did not provide an alternate NDC.

The remaining appeals contained one of several different resolution codes/comments. It is not possible to tell from the data provided how many of these appeals are from the MIA-regulated fully-insured market. However, the information supplied by this pharmacist does support allegations that PBMs do not always provide an NDC as part of a denial. Further, that pharmacies are prevented from reversing and rebilling claims when an appeal is upheld. When upheld, pharmacists argue that they should not be required to rebill or resubmit the same claim.

As stated previously, the MIA had not received many MAC pricing complaints as of the conclusion of the Workgroup meetings, indicating that parties are complying with the processes set forth in § 15-1628.1(f). As stated above, a number of complaints have since been received and are currently under investigation.

The statute does not appear to provide any meaningful assistance to independent pharmacies in locating for purchase a drug at or below a PBM's MAC reimbursement rate.

During the final meeting of the Workgroup, all stakeholders agreed that an NDC does not identify the wholesaler from whom the drug was purchased. An NDC identifies the manufacturer of a specific drug and its dosage and package size, but pharmacists cannot buy directly from manufacturers. Independent pharmacists did state one benefit to receiving an NDC with an appeal denial is that it allows a pharmacy to verify that the code provided is for a valid product which can still be purchased.

3. If an appealed claim is upheld, should the pharmacy be required to resubmit the claim for re-adjudication?

- Under § 15-1628.1(f)(5)(ii), if a pharmacy's MAC appeal is upheld, the PBM must "permit the appealing contracting pharmacy to reverse and rebill the claim, and any subsequent similar claims."
- Independent pharmacies assert the following issues prevent them from reversing and rebilling a claim when they prevail on a MAC appeal:
    - Time involved in the appeals process as currently constructed.
    - The claim cannot be reversed and rebilled if the PBM does not make its upward adjustment to MAC price retroactive to the date the claim was adjudicated.
    - Most PBMs, by contract terms, prevent non-Medicaid claims from being resubmitted by a pharmacy or pharmacist after 30 days have elapsed since the initial claim adjudication. This is problematic because the appeals process may take as long as 42 days if the pharmacy takes the maximum-allowed 21 days to file its appeal and the PBM takes the maximum-allowed 21 days to respond per § 15-1628.1(f)(1) and (2).
    - Transaction costs ranging from $0.06 to $0.18 per claim to reverse and rebill. The pharmacy incurs additional costs to rebill for a claim that was already properly submitted.

Even when the PBM is in error, the statute as written still places the burden on the appealing pharmacy to resubmit the claim so it can be re-adjudicated and properly paid. Even then, the pharmacy may not be able to reverse and rebill the claim, and any subsequent similar claims, because of policies and procedures established by the PBM.

Placing this burden on the appealing pharmacy is inconsistent with state laws governing the payment of claims by health insurers and determinations of medical necessity. For a health insurance claim, once a carrier receives a clean claim and all required elements have been provided to the insurer, that claim must be paid within 30 days. If a claim is not clean or is otherwise in dispute, once enough information has been provided for the claim to be considered clean or end the dispute, payment must be made within 30 days. See, §§ 15-1005(c) and 15-1005(f)(2) and (3). Under this current clean claims law, a patient or provider is not required to resubmit the claim. For prior authorizations involving determinations of medical necessity, if services are initially denied, a member can file an appeal. If the appeal is upheld, services are immediately authorized. The member, member's representative, or the provider acting on behalf of the member, is not required to submit a new utilization review request if all elements of a clean claim have been provided to the insurer.

4. Why should a claim handled by a PBM not be adjudicated and paid at an amount no lower than what the PBM pays its own pharmacies or affiliates?

This question was asked as a result of HB 1103, which would have amended a new § 15-1632 of the Insurance Article. This proposal would prevent a PBM from reimbursing a pharmacy or pharmacist for a product or service in an amount less than the amount the PBM reimburses itself or a corporate affiliate for the same product or service. Throughout the Workgroup's discussions, no participating stakeholder appeared to articulate a valid reason as to why a PBM's affiliates should be reimbursed at a rate lower or otherwise different than the reimbursement rate for other pharmacies. There were comments that PBMs and carriers use many different MAC lists because they need flexibility to provide different benefits to different clients based on customer needs. However, no explanation of the nexus between different benefit plan configurations and actual drug acquisition cost amounts was provided. Caremark asserted that there is an internal wall between it and the affiliated CVS pharmacies, thereby making it impossible for Caremark to compare the reimbursement amounts paid to independent pharmacies versus those paid to CVS pharmacies.

5. National Average Drug Acquisition Cost (NADAC)

- NADAC is calculated pursuant to a federal contract between the Centers for Medicare and Medicaid Services ("CMS") and the accounting firm of Myers and Stauffer. Pharmacies are selected at random to provide invoice-level data regarding their drug acquisition costs.
- NADAC data is updated on a weekly basis every Wednesday; Data files are available at Medicaid.gov.
- Independent pharmacists described the NADAC as a transparent, impartial reference which surveys invoice-level data of both independent and chain pharmacies.
- PBMs asserted that Maryland law is "more aggressive" than the NADAC because PBMs must update MAC pricing information at least every seven days per § 15-1628.1(c). The PBMs claim that although NADAC is also updated weekly, there is still a lag in the data.

6. How does the reimbursement amount based on the NADAC amount compare to MAC reimbursement set forth by the PBM? If reimbursements are higher in aggregate from a MAC list, are NADAC prices useful? If so, how?

- At the fourth meeting, Express Scripts provided the MIA with the executive summary of a study conducted by the Washington State Office of the Insurance Commissioner. According to Express Scripts, this study showed PBMs actually reimburse more under MAC than under NADAC. The MIA reviewed the study and confirmed it shows, in aggregate, PBM reimbursements are higher from a MAC list than from the NADAC. In follow-up discussions, EPIC Pharmacies claimed the study is flawed because it only looked at benchmark MAC lists and not all MAC lists used by the PBMs analyzed in the study.

- Independent pharmacists say they would like to see NADAC become a "transparent floor" for complaints which can be to be used by the MIA in handling complaints filed by the pharmacies. They are not advocating to discard the MAC pricing system and start over or to use NADAC alone to determine reimbursement rates in the fully-insured market. PBM representatives said they would look at this concept.

The stakeholders agreed that if the NADAC is used, it should only be used on complaints filed with the MIA. The MIA further investigated the NADAC between the fourth and fifth meetings. It is not clear that the lag time in the NADAC updates is as problematic as the PBMs claim. There are mechanisms in place through which Myers and Stauffer can investigate and respond to sudden changes in the market in a matter of days and update NADAC as needed.

B. Potential Solutions for MAC Pricing Issue

Throughout its meetings, the Workgroup discussed several potential solutions to the MAC pricing issue, some of which might require action by the General Assembly to modify existing laws and/or enact new legislation. Other potential solutions may be addressed through regulation. Stakeholders failed to reach a consensus, however, on any of the potential solutions discussed. Despite the failure of the stakeholders to reach consensus, this report includes a description of the potential solutions discussed. Please note, however, that the MIA has no position on the solutions included nor does it support or oppose any specific legislative or regulatory action.

1. Potential Changes to § 15-1628.1 of the Insurance Article, proposed by Stakeholders

During the Workgroup's final meeting on November 13, representatives of the carriers and PBMs presented three proposed changes to the MAC pricing statute which they felt might help alleviate some of the concerns of the independent pharmacists. Those proposed changes are as follows:

- Add language, possibly under a new subsection (c)(1), which states: **"A PHARMACY BENEFITS MANAGER SHALL ESTABLISH A REASONABLE PROCESS BY WHICH CONTRACTED PHARMACIES HAVE A METHOD TO ACCESS RELEVANT MAXIMUM ALLOWABLE COST PRICE LISTS IN A TIMELY MANNER."**
- Revise subsection (e)(2) to read, "the drug is generally available for purchase by contracted pharmacies in the State from a national or regional wholesale distributor **AUTHORIZED TO DO BUSINESS IN THE STATE** and is not obsolete."
- Revise subsection (f)(4)(ii) to read "the national drug code of a drug that **WAS AVAILABLE TO CONTRACTED PHARMACIES [**may be purchased by the contracted pharmacy**]** at a price at or below the benchmark price determined by the pharmacy benefits manager; and"

The first proposed change was offered in response to the pharmacists' concerns that they do not have access to the MAC lists and do not know if they will be taking a loss on a

prescription until the moment it is processed. The second change was offered in an effort to provide assurances that any drug which is placed on a MAC list can be purchased from a wholesaler authorized to do business in Maryland. This change would be similar, though not identical, to recent changes to MAC pricing laws in other states, such as Washington, which require PBMs to provide an NDC for a drug that was purchased by other network pharmacies in the state. The final change was offered in response to concerns from the MIA that subsection (f)(4)(ii) appears to be prospective while stakeholders insisted the intent is to look at the price of the drug on the day the claim was adjudicated. The MIA asked stakeholders if additional language could be added to clarify the drug was available "on the date of the initial claim" or "on the date the claim was adjudicated" and further asked if it might be possible to add language to prevent a PBM from listing an NDC which is only available at a PBM-affiliated wholesaler.

The independent pharmacists in attendance were not supportive of these three proposals and argued that, while having access to the PBM MAC lists would be an improvement, such access does not help with day-to-day operations because they do not know what MAC list the PBM is using to determine the reimbursement rates on any given day and because a complaint cannot be filed until there is a claim to adjudicate. The pharmacists further asserted that these proposed changes would not allow them to determine exactly where a drug is available for purchase at or below the MAC price.

PBM representatives countered that disclosing the exact wholesaler would invite legal scrutiny or complaints that the PBMs are steering business to specific wholesalers. The MIA initially agreed that this may be a potentially legitimate concern, but after researching the issue has been unable to locate any statutory or other legal authority under which this would be considered an illegal act.

2. Additional Potential Changes to § 15-1628.1

a. Shift Obligation to Reverse and Rebill the Claim to the PBM

As discussed above, placing the obligation to reverse and rebill a claim from an upheld MAC appeal on the appealing party is not consistent with how other areas of the health care industry are governed under state law. Once a PBM has upheld a pharmacy's MAC appeal, all the information to reimburse the pharmacy in the proper amount already exists and is in the PBM's or carriers' possession. A PBM should be able to pay the pharmacy any additional money owed without the pharmacy having to reverse and rebill the claim. One possible fix would be to revise § 15-1628.1(f)(5)(ii) to read "re-adjudicate the claim based on the higher MAC price for the drug and remit to the appealing contracting pharmacy the proper reimbursement amount, less the amount already reimbursed at the time of the initial claim."

b. Further Clarifications to § 15.1628.1(f)(5)(ii)

In the absence of the above change, this section could be amended to clarify that the pharmacy may reverse and rebill the claim, and any subsequent claims, at the higher MAC price, as follows: "permit the appealing contracting pharmacy to reverse and rebill the claim, and any subsequent **[**similar**]** claims, **AT THE HIGHER MAXIMUM ALLOWABLE COST, AS**

DETERMINED BY THE APPEAL." Such a change would prevent PBMs from determining they actually should have reimbursed the appealing pharmacy less during the time the claim is being reversed and rebilled. Deletion of the word "similar" is also proposed because, in order to be relevant to the appealed claim, a subsequent claim would need to be identical (same drug, dosage, etc.) to the appealed claim. If the General Assembly determines to retain the word "similar" then it should consider giving the MIA authority to promulgate clarifying regulations if needed.

Additional legislative and/or regulatory adjustments may be necessary in light of statements by the independent pharmacists that claims from upheld appeals cannot be reversed and rebilled if the adjustment to a higher MAC reimbursement is not retroactive to the date of the claim. Likewise, the continued use of the word "similar" may lead to confusion.

Another potential amendment to this statute which would further clarify its intent may be to add language that expressly permits a pharmacy to file a complaint with the MIA if it is dissatisfied with the outcome of its appeal to the PBM. In 2016, the Washington State legislature added language to its MAC pricing laws, effective July 1, 2017, permitting pharmacies with fewer than fifteen retail outlets within the State to file a complaint with the Washington State Office of the Insurance Commissioner.

c. NADAC

Expressly establish, via either legislation or regulation, the NADAC price of a drug as the floor for all MAC pricing which can be ordered in cases of complaints filed with the MIA.

d. House Bill 1103: Refusal to Provide Pharmacy Services

During the Workgroup's final meeting, in the context of our larger discussions about MAC pricing reimbursements, the independent pharmacists stated that lost in the debate over HB 1103 was that pharmacies would not refuse to dispense a drug if they would only lose a small amount of money on the prescription or service, such as $0.50 or $1. According to the pharmacists, such a refusal would not be worth their time or the potential loss of a customer. The pharmacists stated they are only concerned about the larger monetary losses they incur. With this in mind, should this legislation be reintroduced, the committee might consider adding a specific dollar amount of loss. If filling a prescription or providing a pharmacy service will result in a certain dollar loss for the pharmacy, then it would be permitted by law to decline to dispense the drug or provide the pharmacy service.

IV. Summary of Specialty Drugs Discussions

A. HB 1117: Specialty Drugs (1st, 3rd, 4th and 5th meetings)

1. Does the definition of "specialty drug" in § 15-847(a)(5) need to be changed?

- The PBMs and carriers assert the current law does not need to be changed. This includes the ability to require use of carrier designated specialty pharmacies and the 4-part statutory definition of specialty drug stated in § 15-847(a)(5). Their stated reasons for the ability to require use of a designated pharmacy and define specialty drugs include: 1) care management; 2) providing mechanisms for enhanced carrier or PBM control in situations where patients are obtaining drugs which require special handling, treatment, or consultation; and 3) the specialty drug law has not been in effect for long enough to know if the law is working as intended. The carriers and PBMs repeatedly stated no independent pharmacists have filed complaints with the MIA, indicating the pharmacists' concerns conveyed were being overstated.
- Carriers state the specialty pharmacy definition in its current form has two important consumer protections built into it with the $150 copay cap and the ability to handle and control patient outreach and support. They state the definition of specialty drug is derived from a 4-part test that is specifically tailored to ensure proper controls over specialty drugs and their dispensing, care management, care coordination and adherence counseling.
- Carriers and PBMs assert that any pharmacy can become a participating pharmacy to dispense specialty drugs as defined, as long as they meet the established credentialing and contracting requirements.
- The independent pharmacists believe the definition of specialty drug is too broad in scope and also that carriers should not be allowed to require member use of a designated specialty pharmacy. They argue that the designated pharmacy requirement effectively walls off certain drugs from the independent pharmacists in commercial insurance plans because they cannot meet the necessary requirements to become a participating pharmacy or designated specialty pharmacy.
- The independent pharmacies also say specialty drugs should be limited to those drugs which require special preparation, handling, or distribution. This should not include drugs for which a simple medication is taken for everyday conditions like high blood pressure, high cholesterol, asthma, gastrointestinal reflux disease, or depression. They argue the 4-part definition is written in each part to be so easily manipulated that carriers and PBMs can deem any drug which is not an antibiotic and costs $600 or more for up to a 30-day supply to be a specialty drug. They state the only reason the $600 portion of the definition is clear is because it is the only standard which cannot be unilaterally altered by the carriers or PBMs. The independent pharmacists also complained the 4-part definition is so subjective that there is no consistency among carriers in the definitions of specialty drugs.
- In support of their argument, the independent pharmacists cited CareFirst's list of specialty drugs as one that has expanded significantly due to CareFirst's ability to broadly interpret the definition of specialty drugs. That list has risen from approximately 52 specialty drugs to over 428 specialty drugs in the last several years. The pharmacists

presented the list of CareFirst's 428 specialty drugs and the MIA asked certain questions about how that list may change if changes in the specialty drug law were made. The pharmacists said approximately 250 of these drugs are limited distribution drugs as determined by the federal Food and Drug Administration, and therefore appropriately classified as specialty. Approximately 100 other drugs on the CareFirst list are only used in an inpatient setting. This leaves a list of 77 drugs which the independent pharmacists stated are all standard distribution drugs under federal standards, and are readily available to the pharmacy within 24 hours from a wholesale distributer.

- The pharmacists stated these 77 drugs are all either orally administered or self-injectable and are drugs which they have the knowledge and expertise to dispense. Therefore, they believe these are specialty drugs, as currently defined, which they should be allowed to dispense or distribute. They also argue that independent pharmacies should be allowed, at the state level, to dispense or distribute drugs which are not under federal limited distribution status, like they are able to do under the Medicaid and Medicare Part D plans, without having to be a designated specialty pharmacy.

2. Is the definition of "complex or chronic" in § 15-847(a)(5)(i) too broad?

- Specialty drug is defined with a 4-part definition as follows:

> "Specialty drug" means a prescription drug that:
>
> (i) is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;
>
> (ii) costs $600 or more for up to a 30-day supply;
>
> (iii) is not typically stocked at retail pharmacies; and
>
> (iv) 1. requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or
>
> 2. requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

- The first section of this 4-part definition requires that a specialty drug be prescribed for a rare, complex or chronic medical condition. The pharmacists argue that the "complex or chronic" condition portion of the definition of specialty drug effectively amounts to at will expansion of the specialty drug list because most conditions fit within complex or chronic. Complex or chronic conditions are physical, behavioral, or developmental conditions that "may have no known cure; is progressive; OR can be debilitating or fatal if left untreated or undertreated[2] [emphasis added]. Again, they argue this should not be for conditions such as high blood pressure, high cholesterol, etc.
- The pharmacists and the Maryland Pharmacists Association also argue that the independent pharmacists do not file complaints because they are then retaliated against by the PBMs through audits and increased scrutiny.

[2] § 15-847(a)(2)(i). There are also complex conditions specified in subsection (ii).

Looking objectively, this portion of statute seems to be written so as to be broad. Specifically, the use of the "or" makes this first part of this definition broad. This was not a subject on which too much time was spent because the parties agreed on this interpretation. For the most part it was the characteristics of the drugs that acted as a main driver of the discussions and debate.

3. Should the $600 cost for a 30-day supply be raised to a higher amount such as $1,000, $1,500, or $2,500? If the $600 threshold is increased, what impact, if any, would this have on the $150 copay cap for specialty drugs and consumer costs such as premiums and cost-sharing?

- Part two of the four part definition states specialty drugs must cost over $600 for a 30-day supply which the pharmacists say is too low a dollar amount. The independent pharmacists state that such a low threshold allows over 400 drugs to be designated as specialty by carriers and PBMs, when in reality that number should be much lower.
- PBMs and carriers argued this $600 amount was chosen to be consistent with the Medicare amount and Medicare has only recently updated to $670. They also argue if the amount is increased the $150 copay cap would need to go up and harm consumers because as the threshold rises so does the copay until the threshold is exceeded. For instance, someone who has a 20% coinsurance payment for a 30-day supply of a specialty drug which costs $950 now only pays $150 out of pocket for the drug per the cap at § 15-847 (c)(1). If the threshold amount was raised to $1,000, that would by definition eliminate this as a specialty drug and remove the copay cap protection. That patient's out of pocket cost would rise to $190.
- Increases to $1,000, $1,500 and $2,500 were explored. Express Scripts indicated if the limit was raised to $1,000 there would be 41 drugs that would no longer be specialty drugs. In addition to the limited distribution drugs, CareFirst would have approximately 60 drugs drop off of its specialty list. That moves up to 75-80 drugs if the amount is raised to $2,500.
- The raising of the $600 limit may make some sense, but the out of pocket cost increases would be borne by the consumers. An argument made by the PBM's was that if the $600 threshold rises premiums may be forced to rise as well. However, if the threshold rises and cost sharing amounts increase with it the carrier or PBM will actually be paying less overall for the same drug. In that scenario premiums should, at least in theory, decrease.
- In addition to the potential consumer cost effects, one of the independent pharmacists conceded that just increasing the $600 amount would not be satisfactory to resolve their concerns. The amount is one piece of the puzzle, but the overall concerns still reside with the subjective nature of the definition as a whole.

4. What constitutes a drug that is "not typically stocked" at a retail pharmacy for purposes of § 15-847(a)(5)(iii)? Who judges what drugs are typically stocked by a pharmacy?

- The independent pharmacists argued this is not really an adequate measure and does not reflect the reality of what happens with specialty drugs. Plus, the subjective nature of the law allows the carrier to determine what is not typically stocked by a retail pharmacy. The independent pharmacies have refrigeration which allows them to stock many specialty drugs just like the designated specialty pharmacies. They also can and do regularly stock drugs for established customers. If a pharmacy regularly keeps a drug stocked to meet the demand of one or a few regular patients, why is that not enough to say it is typically stocked and therefore fails to meet this portion of the definition and cannot be a specialty drug? The independents argued it should, but that the subjective nature of the statute overrules this logic.
- Another question is does "typically stocked" at the pharmacy mean the drug is on hand all the time or instead, simply available onsite within 24 hours? The independent pharmacists say that in the normal course of business an independent pharmacy can have a specialty drug which is "not on the shelf" shipped to and actually in the store within 24 hours. They stated that in many instances all the designated specialty pharmacy does is ship the drug from the specialty wholesaler to the local pharmacy for distribution to the patient. This is also something the independents say they can handle if allowed. They argue that the law should at least allow them to be able to distribute the drug and then notify the carrier it has done so to alleviate its concerns about care management and allow the carrier to perform its care management program.
- The Carriers and PBM's did not really offer much in the way of a response about "not typically stocked" being within the discretion of the carrier other than that there were no complaints filed with the MIA so they do not see this as an issue.

5. What is a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or what drug requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after the administration of the drug?

- The independent pharmacies stated that there are some specialty drugs that they do not have any desire to handle due to the truly specialty nature of those drugs. However, they do not want to be cut out of the market based on determinations of a drug being a specialty drug that do not make sense. They argue that in many cases there are no such difficult or unusual processes of delivery to the patient. Again, in many cases the drug is

subjectively determined to be specialty and then just mailed to the member/patient or to the pharmacy for it to be picked up.

- The main discussion centered on the second part of § 15-847 (a)(5)(iv). The response from carriers and PBMs was that the real issue is the need to be able to effectively handle the care management and medication adherence assistance with the patient. CareFirst discussed the fact that it has nurse care management specialists who contact those who take specialty drugs to provide advice and assistance. The company stated this care management is an essential part of the overall management of the health and welfare of individuals and helps lead to better overall improved treatment results. This was an area in which CareFirst indicated it is not flexible due to the importance of its care management for patients.
- The independent pharmacies say they can do these same things and help provide care management if they are allowed to do so. They state they can dispense the specialty drug, advise the patient about any specialty drug specific issues, answer patient questions, and otherwise provide advice, sometimes even more effectively in person.

6. Are licensed pharmacies capable of being designated as "specialty" pharmacies for the purposes of dispensing specialty drugs and do current carrier performance standards prevent pharmacies from being able to become a participating specialty pharmacy?

- Independent pharmacies claim that the process of applying to become a designated or participating specialty pharmacy within a carrier or PBM's specialty pharmacy network is cost prohibitive and risky because two accreditations are typically required. They also state they are already subject to state licensing requirements which are acceptable for participation in the Medicare and Medicaid markets. They state that a URAC accreditation application is lengthy and costs approximately $30,000 for a three year accreditation. An independent pharmacy could apply and pay the URAC accreditation fee, the second accreditation organizations' fee, and then, for example, not be accepted by CareFirst as a participating pharmacy for a number of reasons.
- The CareFirst representative acknowledged that this was possible. She stated that to be a participating specialty pharmacy requires the two accreditations and agreement to the CareFirst provider contract, including all financial and payment terms. CareFirst requires two accreditations from health care accreditation organizations, including one from URAC. There are three other accreditation organizations that have accreditations standards for pharmacies. They are JCAHO, ACHC, CPPA. JCAHO accreditation costs approximately $7,000, and ACHC costs between $7,000-$10,000.
- CareFirst and its PBM, Caremark, again stated that no independent pharmacies have applied to become a specialty pharmacy within the network.

B. Possible Solutions for the Specialty Drug Issues

1. Have some type of independent third party determine what constitutes a specialty drug. An independent source could either determine what is a specialty drug per the statutory criteria of § 15-847(a)(5) or alternatively follow the designations made by the Medicare or Medicaid programs. This would take the decision making ability away from the carriers and PBMs who may have a real or perceived financial interest in deeming a larger portion of the drugs on the market as specialty along with the ability to direct that business to certain designated or participating pharmacies.

2. It is important to note that the carriers and PBMs were strongly against any changes to the definition of specialty drug. They argued that this particular law has not been in effect a long enough to see if it works as intended. Further, changing the definition will have larger implications beyond just patient prescription because it will impact overall care management and patient outcomes. Changing the definition of Specialty Drug at § 15-847(a)(5) to remove some of the subjectivity that the independent pharmacists perceive and object to include:

    a. Defining complex and chronic to be more definite in § 15-847(a)(2)(i). If the statute removed "may have" from "may have no known cure" in 1., and replaced it with "has no known cure", and/or changed "can be debilitating" to "is likely to be debilitating" in 3, some of the subjectivity could be removed from that definition.

    b. Provide some specificity to the definition of "not typically stocked at retail pharmacies" so that an accurate measure can be utilized by those seeking to determine whether a drug is appropriately classified as a specialty drug. Retail pharmacies can be vastly different in size, character, clientele served, etc. There really is no way to tell what a typical retail pharmacy is for purposes of § 15-847(a)(5)(iii). Retail pharmacies typically have the ability to handle refrigeration needs. If "not typically stocked" is intended to mean not part of the retail inventory except in extremely rare circumstances which require more than just refrigeration that clarification would eliminate some subjectivity.

    c. Require both sets of criteria stated in § 15-847(a)(5) to be present as opposed having it be an either or. This would mean a drug would need to have a difficult or unusual process of delivery to the patient and require

the patient to need more than normal education, management, or support for the drug dispensed.

d. Raising the $600 limit. There were several discussions and follow up discussions about changing this amount. The overall sense of the MIA is that changing the number may be the easiest thing to accomplish legislatively. This could also yield some immediately quantifiable relief in the short term for independent pharmacists depending on how high the cap moves. However, this change would have the most obvious negative impact on some consumers by removing some drugs from the protection of the $150 co-pay cap.

e. Adopting a more wholesale change and moving to a simplified definition like North Dakota, which says a specialty drug is: 1) any drug not available for order or purchase by a retail community pharmacy; AND 2) requires special storage and has distribution or inventory limitations not available at a community pharmacy. This change would align with what the independent pharmacists contend is the traditional meaning of a specialty drug. That is, a drug that requires handling and storage that is outside the handling or storage capability of a retail pharmacy. Although simplified, this definition could also potentially be partnered with the portion of § 15-847(a)(5)(iv)(2) to keep the care coordination as part of definition if the carriers so desired.

3. Prohibit carriers or PBM's from requiring more than 1 accreditation from a nationally recognized accrediting body for prescription drugs to become a designated or participating specialty pharmacy. This particular option is difficult to assess because of the lack of specific insight into the different organizations accreditation requirements. The MIA was able to secure the requirements from the ACHC's standards for Community Retail Pharmacies but had no other standards to compare them to even though we heard regularly that URAC standards are recognized as the "gold standard" for accreditation for pharmacies.

4. Give the MIA authority to promulgate regulations to address issues that arise out of the statute and/or review for approval the participating provider agreements between the carriers, PBMs, and network pharmacies.

V. HB 1162: Fees Not Specified at Time of Claim

A. Direct and Indirect Imuneration (DIR) Fees

The final issue addressed at the stakeholder meetings was the growth of DIR fees which are being charged to pharmacies in the Medicare Part D market. These DIR fees are part of incentive programs which are written into the participating pharmacy contracts which also have a disincentive side for lower performing pharmacies.

- HB 1162 was introduced to address concerns raised by independent pharmacies that the PBMs or carriers would start implementing the DIR fees in the commercial insurance markets. More specifically, the bill would have prohibited PBMs or carriers from directly or indirectly charging a contracted participating pharmacy, or holding such a pharmacy responsible for fees which were not enumerated or specified at the time of the claim adjudication or reported on the initial remittance advice of an adjudicated claim. The independent pharmacists stated that these fee amounts can sometimes be as high as 30% of the drug reimbursement amount paid to the pharmacy.
- All stakeholders acknowledged that his practice is not currently occurring outside of Medicare Part D plans. However, because these fees are allowed per their participating provider contracts with the PBM's, the independent pharmacists stated that they need to be proactive to prohibit the implementation of the use of these unknown fees which are charged after the fact. They argue that once they are implemented by the PBMs in the state insurance markets it will be an almost impossible uphill battle to get DIR fees stopped.
- The independent pharmacies shared that in Part D, the DIR fees are sometimes assessed between 90 to 180 days after a claim is adjudicated. As a result, the late assessment of the fees after the claim is adjudicated makes it difficult to engage in business planning. Moreover, while DIR fees are designed to reward top-performing pharmacies and penalize those pharmacies that perform poorly, the independent pharmacies reported that even top performing pharmacies are assessed DIR fees.
- The independent pharmacies argue that if the consumer is charged a cost sharing amount at the pharmacy based on the initial drug price, but the amount paid to the pharmacy is reduced by the PBM assessing a DIR fee 90 days after the fact, thereby reducing the claim cost of the drug for the carrier, that the consumer does not share in the price reduction. The consumer does not share in the reduction on the individual claim. Further, unless these fees are credited back to the carrier account, the consumer does not share in any portion of the reduction which assists with premium reduction at the overall carrier level.
- The independent pharmacists noted that similar legislation was passed in Louisiana, RS 22:1860.2, preventing a health insurance carrier or PBM from directly or indirectly charging or holding a pharmacist or pharmacy accountable for any fee related to a claim: (1) that is not apparent at the time of the claim processing; (2) that is not reported on the remittance advice of an adjudicated claim; (3) after the initial claim is adjudicated; or (4) in order to participate in a specified provider network.
- The carriers and PBMs stated that there are no current plans to implement these DIR fees in the commercial markets but acknowledged that this could change. They stated that the

contracts provide for these types of fees in the Part D market as part of an incentive-based program in which pharmacies participate.

B. Possible Solutions for the DIR Fees

The MIA recognizes that this is not an active issue. The independent pharmacists stated what appear to be legitimate concerns that DIR fees could be expanded to the commercial prescription drug insurance markets.