REPORT TO THE NEW MEXICO INTERAGENCY PHARMACEUTICAL PURCHASING COUNCIL:

Recommendations for the Work of the Council

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NOTE: This report was revised on 3/1/2020 based on new data from the State Medicaid agency about the average rebate percentage for fee for service Medicaid, discussed in the subsection that begins on page 9.

Introduction

This report provides recommendations to the New Mexico Interagency Pharmaceutical Purchasing Council (IPPC) for how it might start its work to constrain the rising cost of prescription drugs for public and private entities as directed by the 2019 New Mexico law, SB131.

The recommendations in this report for IPPC consideration are divided into five sets: recommendations for payer spending, recommendations for Medicaid, recommendations for direct purchasers of drugs, broad recommendations/considerations that span across state market segments, and recommendations to include private sector payers and purchasers in the State's prescription drug cost containment initiatives.

Context

Like New Mexico, a growing number of state governments are searching for new ways to constrain the growth in state government spending on prescription drugs. The work of states is very varied as highlighted below:

- Some states intend to align state and/or local government-funded health plans for greater market leverage.
- Some states intend to consolidate drug procurement for state entities that directly purchase drugs.
- In Medicaid, states are testing a variety of approaches:
    - pulling the pharmacy benefit out of managed care contracts to have better oversight of pharmacy benefit manager (PBM) services and to have a stronger hand negotiating supplemental rebates (New Mexico has no supplementals); or
    - experimenting with value-based contracts with manufacturers for very high cost drugs; or
    - examining how the 340B-eligible program providers are billing Medicaid to ensure compliance with complex rules that are difficult to audit.
- States are examining the deep discount 340B prescription drug program and asking certain questions.
    - Can state corrections departments leverage the program's deep discounts to lower pharmacy spend and improve access?
    - Can state payers work with 340B entities to share in the drug cost savings when enrollees are treated at 340B facilities?
- States are starting to consider whether a multi-state purchasing strategy can produce cost savings.
- States are exploring if and how to unite government and private sectors in drug procurement and/or pharmacy benefit management contracting.

Many of these explorations are also found in the legislative remit for the IPPC.

Traditionally, prescription drug manufacturers provide price concessions based on the payer or purchaser's ability to 'move' market share away from a competitor to the product of the negotiating manufacturer. This can be accomplished if the payer excludes coverage of a competitor product altogether or it can be accomplished by 'preferring' a drug relative to a competitor— placing the preferred drug on a lower formulary patient cost sharing tier. Lower patient out of pocket costs are thought to improve patient treatment adherence and sales, with or without excluding a competitor.

However, the price of drugs has become increasingly challenging. At the same time, more drugs come to market with less and less clinical efficacy data and are designed to treat smaller patient populations.

In this context, the older tools by which to leverage price concessions are less satisfactory, less applicable, or less suitable to the evolving market. Therefore payers, purchasers, and patients are struggling to manage drug costs.

Common Pharmacy Benefit Tools

State and commercial payers have used a variety of tools to manage the outpatient pharmacy benefit – tools that are becoming less useful as new pharmaceutical products come to market.

The more traditional tools include prior authorization, quantity limits, preferred pharmacy networks and pharmacy reimbursement formulas, as well as patient cost-sharing and manufacturer rebates. These tools for managing the retail pharmacy benefit have been relatively successful for managing retail pharmacy drugs that are used across a broad population where there are several therapeutically similar drugs and a large patient population (diabetes, hypertension, cardiovascular disease, for instance). Among manufacturers of therapeutically similar drugs, there is some level of market competition such that a manufacturer will want to deter utilization management against its products by providing rebates to health plans or the health plans' pharmacy benefit managers (PBMs).

But as the market moves more to specialty drugs – high cost, complex biopharmaceutical products for treatment of relatively small populations with unusual diseases – the traditional pharmacy utilization management tools are not as effective in constraining costs as they are for large population, retail pharmacy drugs.

Traditional tools are less effective for several reasons. Manufacturers of high cost drugs use the patent system to prolong the period of patent protection for a drug which delays entry of generic competitors. Patent protection runs for 20 years from the date the patent application is approved, which is many years before a drug can be licensed for market. Historically, a drug comes to market with maybe ten years of patent protection remaining.[1]

In addition to patent protection, there is protection of clinical data, known as "data exclusivity." This protects the clinical trial and other research data from being shared or made public. The clinical data can be useful or even essential to creating a competitive product. Data exclusivity protections start on the date the product is approved for market by the Food and Drug Administration (FDA). Brand products that are not biologics have data exclusivity for five years. Biologic products have data protection for 12 years. In this case, data protection can last longer than the patent protection for a drug on the market. Clinical research data is very important in creating lower cost biosimilars. Data exclusivity increases the number of years until a biologic has market competition.

As we head toward a new era of highly individualized treatments, such as extremely costly gene therapies, traditional cost containment activities are less and less effective for the drugs are that driving up medical benefit and pharmacy benefit costs.

[1] The average length of patent protection remaining once a drug comes to market may be changing since there are several expedited pathways to market approval which limit the amount of data or the research endpoints, either of which can speed up drug development for many newer products.

With that said, it is still worthwhile for health plans and purchasers of drugs to ensure that they are maximizing cost containment, making sure that the lowest cost, most appropriate prescription drug is being dispensed or administered to the right person at the right time.

Terminology

There is a glossary of terms at the end of this paper. But in order to get the most out of this paper and to optimize IPPC investigation, discussions and deliberations, it would be most helpful for the IPPC to use two key terms distinctly and consistently. The terms "purchaser" and "payer" are often used interchangeably. This interchangeability is fine for a very general, high-level discussion of drug spending and drug costs (such as "state drug purchasing"). However, in discussing how to improve State government spending on prescription drugs, payers and purchasers have distinct operational differences and confront the cost of prescriptions very differently. These differences must be front and center in any IPPC research and policy deliberation.

The policy recommendations of the IPPC can address and improve spending for both payers and purchasers so long as the IPPC understands and works with the differences. Lack of distinction of stakeholders in serious and detailed discussions can really bog down the work.

Purchasers are entities that buy, stock, and dispense (or administer) drugs to patients. With some exception purchasers seek payment for their professional time treating patients and seek reimbursement for their costs to buy the drug that was dispensed. In the context of State government purchasers, the purchasers such as Department of Corrections or Department of Health facilities do not seek health insurer reimbursement for services and products. A list of IPPC purchasers can be found in Appendix D.

Payers are entities that reimburse purchasers for their professional time and the cost of the drugs used in treatment, otherwise known as health plans. A list of IPPC health plans can be found in Appendix D.

Additionally, some New Mexico entities such as University of New Mexico Health System are both payers (for their employee health benefits) and purchasers (stocking drugs for inpatient and outpatient administration and dispensing).

It is important to not lump these two different sets of stakeholders together in IPPC discussions unless it is fully intentional and appropriate in context.

The Basics

The IPPC policy deliberations will benefit if each member understands the operational aspects of pharmacy benefits and services in their own programs and facilities. It will also be important to be familiar with some data points about your own programs and facilities:

- whether the IPPC member is a payer, a purchaser, or a hybrid;
- the top twenty (or so) drugs with the highest spend by cost and utilization;
    - the *net* cost to you of your top twenty (or so) highest spend drugs;
    - which of the top 20 drugs are retail, physician administered, or inpatient (if billed separately);
- the retail pharmacy dispensing fee(s) paid by your department, agency or facility;
    - any different dispensing fee amounts for different drugs or different pharmacies; and
- key provisions of your PBM or other pharmacy services provider contracts – fees, ingredient cost payment formulas, termination provisions and any performance audit provision of the contract.

Less relevant to IPPC consideration in the early stages of the work will be enrollee/participant/resident cost sharing. The greatest impact of IPPC work is likely to be reduction in the net cost of drugs for payers and purchasers. Lowering cost sharing can flow from success in lowering the actual cost of drugs.

New Mexico Government Health Plans (payers)

This section compares some of the initial data reported by IPPC member health plans (payers) about their drug spend. The grouping includes New Mexico Medicaid managed care organizations (MCOs) and Medicaid fee for service pharmacy benefit information since these are 'payers' represented on the IPPC. A summary of the purchasers' data (as distinct from payer data) is in a later section of this report.

The ten health plans represented by IPPC members contract with four different PBMs (including Medicaid MCOs and Fee for Service):

- 5 Express Scripts contracts (ES is owned by the health insurer, Cigna)
  - All 5 Express Scripts contracts are with New Mexico government employee health plans
- 1 Optum Rx contract (Optum is owned by the health insurer, UnitedHealth)
  - The Optum contract is with a Medicaid managed care plan
- 2 Prime Therapeutics contracts (Prime has been purchased by Express Scripts)
  - 1 Prime contract is with the UNM employee health plan
  - 1 Prime contract is with a Medicaid managed care plan
- 1 Envolve Pharmacy Services contract
  - This contract is with a Medicaid managed care plan
- 1 Conduent contract
  - This contract is with Medicaid fee for service

Commonalities Among IPPC Health Plans' Pharmacy Spend[2]

COSTLIEST DISEASE STATES REPORTED BY IPPC PLANS	# OF IPPC PLANS REPORTING DISEASE STATE AS ONE OF 5 MOST COSTLY	HIGHEST SPEND RX ASSOCIATED WITH TOP SPEND DISEASE CONDITIONS
DIABETES	10	Trulicity (3 plans) Humalog (1 plans) Novolog (2 plans) Lantus (1 plan) Levemir (1 plan) Basaglar (2 plans)
CANCER	8	Revlimid (4 plans) Imbruvica (2 plans) Imbrance (1 plan)
INFLAMMATORY	8	Humira Pen (9 plans) Enbrel Sure Click (1 plan) Stelara (2 plans)

[2] Top five conditions reported was not always correlated with top five spend drugs. A plan may report diabetes as the top medical condition, but anti-diabetic medications did not make the list of top five highest spend drugs. Another plan may report diabetes as one of the top-five medical conditions and may have more than one diabetes treatment in their top five high spend drugs.

HIV	7	No HIV Rx was reported in top 5 highest spend Rx for any plan
MULTIPLE SCLEROSIS	5 (all employer plans)	Gilenya (2 plans) Tecfidera (2 plans) Aubagio (1 plan)
HEPATITIS C	3 (all Medicaid)	Mavyret (4 plans)
SUBSTANCE ABUSE TREATMENT	3 (Medicaid)	Suboxone (3 plans)
ASTHMA	2 (all Medicaid)	No asthma/COPD Rx was reported in top 5 highest spend Rx for any plan
BLOOD THINNERS	1 (employer)	Xarelto (1 plan) Eliquis (1 plan)
HEMOPHILIA	1 (employer)	Kovaltry (1 plan) Idelvion (1 plan) Adynovate (1 plan)
PAIN	1 (Medicaid)	No pain Rx was reported in top 5 highest spend Rx for any plan
SEIZURES	1 (Medicaid)	No anti-convulsant Rx was reported in top 5 highest spend Rx for any plan
INFECTIONS	1 (employer)	No anti-infective Rx was reported in the top 5 highest spend Rx for any plan

Symdecko, for treatment of cystic fibrosis, was in the top five costliest drugs for one plan, but cystic fibrosis was not one of the top five costliest conditions reported by any plan. Similarly, Tamiflu was one of the top five highest spend drugs for one plan, but influenza was not among the top five costliest conditions reported by any plan.

Rebates Among IPPC Payer Members

In addition to the above information, the average rebate amounts among the ten health plans were reported to range from four percent of total pharmacy spend to almost 33 percent. The rebate amounts for Express Scripts contracts among employer plans ranged from 23.7 percent to 32.6 percent as reported by the employer plans. The employer plan contracted with Prime Therapeutics had an average rebate amount of 10.7 percent. The level of average rebates was not well correlated to the number of covered lives. There are, of course, multiple reasons for the range of rebates among the plans other than plan size. Further study of the differences could be instructive.

In the Medicaid program, the average rebate among managed care plans ranged from 3.2 percent to 4.9 percent while the fee for service program average rebate amount was 54 percent. Low managed care rebates are likely because the Medicaid agency bills manufacturers for the federal law rebate (minimum of 23.1 percent for brands and 13 percent for generics) for the drugs paid for by the Medicaid managed care plans (as well as fee for service utilization). Manufacturers are not inclined to provide deep rebates to Medicaid managed care plans for the same drugs for which they are paying deep rebates to the State. But further exploration would be needed for more clarity about the reported average rebate amount percentage. The fee for service average rebate amount is consistent with federal data and analysis

Recommendations for IPPC Payers

Recommended Step 1:

An independent review of each IPPC PBM contract could be worthwhile because of the overlap in spending patterns, the distinct diversity of top-spend drugs for the same disease state, and the diversity of average rebate as a percent of total pharmacy spend from the same PBM contractor. The review should include:

- contract provisions that may disadvantage or otherwise not advantage the health plan payer;
- formulary designs (drugs covered, the tiering, the rebates received by the plan for the different drugs [notably the high cost products]);
- contract termination provisions; and
- pharmacy network participation requirements and reimbursement methodology (which may or may not be in the contract) should be reviewed.

Recommended Step 2:

Audit the financial performance of each of the contracts through an independent contractor. There are firms that specifically do this type of work. If the audit indicates that current IPPC contracts are not performing well, this finding may create an opportunity to work with the current PBMs to improve performance or to get the utilization 're-priced' by other PBMs or consultants.

Recommended Step 3:

Review procurement procedures for each IPPC payer agency to determine if there are rules or laws that could stymy multi-agency PBM contracting or other multi-agency efforts. If there are barriers to joint procurement, determine if new state code is needed to allow collaborative contracting.

Recommended Step 4:

Determine if there is a desire and ability to consolidate payer PBM contracting into one contract. The bid solicitation should consider any drugs that are of significant financial import to different IPPC plans; this could ensure that no agency's costs increase as a result of a new multi-agency plan.

The IPPC should consider hiring a vendor to administer the PBM bidding process and possibly employ what is known as a 'reverse auction'. The State's vendor would solicit PBM bids after the PBMs have received representative pharmacy claims data from IPPC payer from a recent time period. The bidding occurs in multiple rounds; bid prices decrease in each round. (This in contrast to the normal effect of an auction, where the price increases with each bidding round.) For each round of bidding, the benefit to the different IPPC health plans should be assessed. There are certain vendors with the IT necessary to run a real-time bidding process.

Recommended Step 4a:

IPPC payers should consider whether the structure of their PBM contract(s) which focus on *net costs* via rebates may (unwittingly) impede achieving lower drug prices in the market. If PBM contract performance metrics include the requirement to achieve a certain average rebate as a percentage of total pharmacy spend, the contract structure and provisions could actually cause a PBM to prefer a higher cost drug with rebates rather than a lower cost drug in the supply chain that would lead to lower claims payment for the health plan.

There have been media stories where a manufacturer wanted to come to market (or did come to market) with a list price lower than competitor products but the initiative was not appreciated by PBMs. The result is that the lower priced product struggled in the market and in another case, the manufacturer was reportedly told by a PBM that the product would get a preferred formulary position with a higher price and a rebate. A lower price drug with no rebate adds to the total pharmacy spend but does not necessarily help the PBM achieve its target average rebate as percent of spend. This is a particular problem when PBMs have contracts and contract obligations in place and a new, costly drug comes to market in the contract period.

All of this is complicated, but there is a quite a need to dig into the complexity. Payers need to be sure their contracts are structured to achieve financial goals and policy goals. Payer contracts with PBMs need to be structured to take advantage of any opportunity for lower priced drugs in the marketplace.

Recommended Step 4b:

Note that Medicaid could participate in the multi-agency PBM contracting program for the fee for service pharmacy benefit, or for both the fee for service and the managed care pharmacy benefit as well. Because federal law specifies the minimum rebates/price concessions each manufacturer must pay Medicaid, participation in a multi-agency PBM bid could be conducted as a supplemental Medicaid rebate agreement — rebates above the federally required rebates — as permitted by federal rules.

For Medicaid to participate, there would be something akin to a concurrent, but dual, bid process. The Medicaid approach as part of the dual bid approach can be developed more fully as the IPPC decides on the processes and policies it wishes to pursue.

Unlike most states, New Mexico Medicaid does not have any supplemental manufacturer rebate agreements, and does not participate in any of the three Medicaid multi-state supplemental purchasing groups, so New Mexico Medicaid has some room to strengthen its rebate/price concession contracting and joining in a multi-agency approach may fill in the gap.

Recommended Step 5:

Review information on State entities that participate in the deep discount “340B program” (the program is more fully described in an appendix to this document). These entities obtain prescription drug price discounts equal to, or better than, federal Medicaid rebates. Despite low acquisition cost, 340B entities tend to bill health plan payers at market rates. The difference between their low acquisition costs and their billed amounts contribute to their overall revenue stream, sometimes very significantly so.

The IPPC could identify all the enrollees in IPPC plans treated at 340B entities and then track back to the pharmacy claims related to those visits. This would indicate how much pharmacy spend is in the 340B channel among IPPC payers.

If the pharmacy spend related to 340B facilities, New Mexico government payers could consider negotiating with certain 340B entities to share in some portion of the cost savings when a 340B entity treats an enrollee of a state program.[3]

Recommended Step 6:

Chain pharmacies most likely have access to better pricing/lower costs to stock their pharmacies relative to independent pharmacies and regional chains. If State payers reimburse all pharmacies using national average drug acquisition cost data such as average wholesale price or the National Average Drug Acquisition Cost (NADAC) database, State payers may be overpaying national chain pharmacies and/or underpaying local pharmacies. The NADAC file is thought to most closely reflect the acquisition costs of independent pharmacies, which are thought to be higher than the acquisition costs of national chain pharmacies. There could be savings in calibrating claims payment to better reflect the different acquisition costs of Walgreens and CVS relative to the acquisition costs of New Mexico's independent pharmacies. Even if there are no specific savings, such a calibration could establish some greater equity in the payment system.

Recommended Step 7:

Drugs administered in clinical settings (rather than dispensed in a retail pharmacy) are often very expensive – even to the administering provider. These are often called 'specialty' drugs because of any combination of the following: high cost, complex shipping and handling, complex administration of the drug, and/or need for patient case management. Often, specialty product is synonymous with high cost if nothing else.

Payers may want to explore the possibility of establishing a limited number of outpatient provider sites that can be reimbursed for administration of a particular specialty drug (some specialty drugs require an inpatient stay for the drug administration). It could also be worthwhile to explore whether 340B sites could become specialty centers for some specialty drugs, with the implication that State payers may be able to benefit from shared savings on the drug product. There are 300 New Mexico hospital outpatient clinics enrolled in the 340B programs as reported on the federal 340B website.

It is important to note that any drug used in the outpatient setting can be a 340B drug. It is also important to note that inpatient drugs purchased by certain 340B disproportionate share hospitals are not limited by complex Medicaid rebate rules in the level of discounting they can obtain. Thus, it is possible that costly therapies administered on an inpatient basis could be discounted as heavily as an outpatient 340B-eligible drug. If so, State payers may be able to create limited provider networks for certain high cost therapies that are established around 340B entities.

[3] Medicare Part B is reducing hospital outpatient payments by 22.5 percent for separately billed 340B drugs applicable to several different Medicare hospital type designations. The hospitals are required to identify 340B drugs in their billing. This is an average reduction nearly the same as the Medicaid minimum federal rebate; the savings on some drugs is much higher.

Special Considerations for Medicaid in an IPPC Payer Strategy

The Medicaid Drug Rebate Program (MDRP) was established under federal law in 1990. The law ensures that Medicaid programs obtain prescription drug discounts on par with the best discounts in the marketplace (the so-called best price rebate) or, if there are no terrific discounts, Medicaid would at least get a certain minimum percentage discount off what could be considered the wholesale price.[4]

The rebate amount for Medicaid is also used to establish the minimum federal manufacturer discount to 340B providers -- called the 340B ceiling price. However, 340B entities often get discounts deeper than the federal Medicaid rebate amount through the negotiation of the 340B group purchasing organization (GPO, called the 340B "Prime Vendor") which negotiates additional discounts on behalf of participating 340B entities.

340B entities are required to bill Medicaid at the 340B acquisition cost (which is presumably at the ceiling price rather than at the more deeply discounted GPO price) or not use 340B product and bill market rates for drugs dispensed to Medicaid enrollees. Contract pharmacies (retail pharmacies that contract with 340B entities to expand the volume of drugs through the program) are not supposed to use 340B drugs for Medicaid fee for service enrollees at all, but compliance can be difficult to ascertain. Finally, 340B entities are not required to bill their acquisition cost for Medicaid managed care enrollees. Because the 340B program has moved to a paper tracking system rather than a product replenishment system that segregates actual product on the pharmacy shelves, and because many 340B entities hire vendors to manage tracking of 340B dispensing, it is not always clear that 340B entities are in full compliance relative to Medicaid. It would be good to check on the New Mexico Medicaid claims adjudication process to ensure that 340B providers and their contract pharmacies are in compliance.

Additionally, as mentioned previously, it seems that New Mexico Medicaid fee for service does not negotiate supplemental drug rebate contracts directly with drug manufacturers. These "supplementals" are permitted by the federal rules and each agreement must be approved by the federal government. And, just as applied to the regular federal drug rebates, the federal government shares in the supplemental rebate payments in proportion to its share of New Mexico Medicaid spending (~73 percent of all New Mexico Medicaid spending is paid for by the federal government, so the federal government claims 73 percent of all rebate revenues as well.)

In addition to any IPPC initiative in which Medicaid participates, New Mexico Medicaid might want to consider some of the following approaches specific to Medicaid alone. These decisions may inform the role of Medicaid in any broader IPPC initiatives going forward.

Recommended Step 1:

Pursue supplemental rebates. There are three multistate Medicaid rebate pools, two operated by Magellan and one operated by states (Sovereign States). State Medicaid can belong to more than one group and can come and go from any of the three Medicaid drug supplemental rebate groups.

[4] The Medicaid discount is a rebate from the manufacturer to the State after the drug has been dispensed and the pharmacy reimbursed. The basis of the rebate is the Average Manufacturer Price (AMP) which is calculated according to federal rules. It is close to the commercial WAC so for purposes of this discussion, the WAC will be used since it is a more common term.

Supplemental rebates are important to Medicaid because they provide an additional opportunity to gain price concessions from manufacturers. Supplemental rebates do not have any effect on federal law governing manufacturer rebates.

Recommended Step 2:

Undertake a review to determine if 340B entities, Medicaid managed care entities and Medicaid fee for service are all in compliance with the complex federal laws for billing and paying 340B claims as well as in compliance for Medicaid billing manufacturers for rebates.

States are looking more closely at 340B compliance, which can lower up-front pharmacy claims payment costs on par with the net cost to Medicaid after the back-end rebates.

Recommended Step 3:

New Mexico Medicaid may want to explore whether there is a financial benefit to having all 340B entities use 340B product to dispense to Medicaid enrollees and then bill Medicaid at 340B acquisition cost. At least one state is reviewing 340B entity drug claims against the Medicaid net cost after rebates to see that 340B providers are billing at something close to actual acquisition cost (the 340B ceiling price). The state has decided it prefers reduced up-front claims payment spending rather than reduced net spending via post-dispensing manufacturer rebates. Depending on how Medicaid rebate funds are accounted for or allocated in the State budget, it may be preferable to reduce Medicaid drug paid claims expenditures.

Recommended Step 4:

Medicaid fee for service pharmacy programs are known to promote the use of brand drugs rather than generic drugs. The thinking is that the federal rebates (and perhaps supplemental rebates) reduce the net cost of a brand drug to less than the cost of a generic. Medicaid may want to contract with the State University or other analytic entity to determine whether it is more advantageous for Medicaid fee for service to prefer brand name drugs over generics (which also have base rebates and inflation penalty rebates like brands). Because the rebate program is complicated, some serious review might be worthwhile – even if it confirms exactly what the State is doing.

The State might find that it is financially advantageous to continue to prefer brands until there are two or more manufacturers of the product. Preferring generics may be a policy goal as well as a financial goal.

Recommended Step 5:

State Medicaid programs have gone back and forth over the years about whether to ‘carve in’ or ‘carve out’ Medicaid pharmacy benefit from Medicaid managed care contracts. As drug costs continue to grow and the ability of smaller groups to negotiate pricing relief declines, it may be a financially beneficial to consolidate prescription drug negotiations into the State fee for service program.

Alternately, Medicaid could require Medicaid managed care organizations to have a “unified” formulary where covered drugs and the utilization management applied to the drugs are the same for all managed care organizations and fee for service.

New Mexico Medicaid may want to take a close look at the options while understanding that the decision will be contingent on several factors, including potential IPPC policy decisions about State prescription drug spending, such as unified PBM contracting across all IPPC payers. The carve in/carve out decision would also be influenced by a New Mexico Medicaid decision to require 340B acquisition cost billing in fee for service, in which case the financial benefit of that decision could increase if pharmacy was pulled out of the managed care program.

New Mexico IPPC Government Purchasers

As discussed earlier in this paper, direct purchasers are entities that procure a prescription drug, take ownership of the drug, and then dispense or administer the drug to patients. Most Department of Health facilities (hospitals and residential treatment facilities) and Children Youth and Families Department juvenile justice facilities buy and stock medicine for in-house dispensing. A few facilities also contract for pharmacy dispensing services for drugs that are not stocked in-house. In general, they source their drugs with wholesalers that have contract agreements with Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP Infuse).[5] The off-site pharmacy dispensing services (which also do wholesale stocking) are contracted via MMCAP Infuse.

Contract pharmacy services present the same set of issues as payers face in terms of pharmacy claims – what is the reimbursement formula for various pharmacy product reimbursements and what is the dispensing fee? Are the billings/payment and dispensing fees competitive? How do they compare with the experience of other New Mexico government payers?

Department of Corrections

Medical care at adult correctional facilities is contracted out to a Wexford Health Sources, a national organization specializing in healthcare for correctional facilities. Wexford subcontracts pharmacy services out to Boswell Pharmacy Services which also specializes in pharmacy services in correctional facilities. These contracts come through MMCAP vendor lists and relationships.

Department of Corrections makes bundled payments to Wexford for the provision of all necessary medical care for each person in the system. Top-spend drugs for Corrections include three hepatitis c treatments, Lantus insulin, and Humira for autoimmune conditions.

Children Youth and Families Department

Juvenile Justice facilities currently use Sapphire Pharmacy Services which, like services used in Corrections, specializes in serving correctional facilities. Juvenile facilities now provide routine medical care and pharmacy services by in-house medical staff.[6] Juvenile facilities purchase wholesale from Sapphire which ships drugs that are stocked on-site. The top spend drugs are generally generic and treat asthma and acne/skin conditions. The relationship with Sapphire is a result of membership in MMCAP.

Department of Health

Outpatient Clinics

The New Mexico Department of Health purchases and stocks large quantities of prescription drugs in its warehouse which supplies Department health clinics. The major supplier is Cardinal which is also a supplier for the 340B program. Most of the product for the Department stocking comes through the

[5] MMCAP Infuse is operated by the State of Minnesota. It is a group purchasing organization for prescription drugs and medical services supplies for healthcare institutions and residential facilities. Member organizations must be part of a state or local government and must be non-profit. Most if not all New Mexico DoH and DoC facilities are MMCAP Infuse members.

[6] Juvenile Justice switched from Wexford/Boswell to Sapphire when it brought medical and pharmacy in-house.

deep discount 340B program for its clinics that treat tuberculosis, sexually transmitted diseases, or that provide family planning services.

Residential Facilities

In addition to outpatient clinics, the Health Department provides in-house pharmacy services at various residential facilities such as veterans residential care, substance use disorder treatment residential facilities, intermediate and long-term residential care, as well as adult and adolescent behavioral health residential treatment. Most facilities use Cardinal Health as the wholesaler for their in-house pharmacy services. These facilities are not 340B eligible, unlike many Department outpatient clinics. Most if not all the facilities accessed Cardinal through membership in MMCAP Infuse.

The Veterans Home has three contracts for wholesale purchasing. They can access the federal Department of Veterans Affairs federal supply schedule discount drug vendor, the MMCAP Cardinal vendor or a third contract with McKesson. Staff check the price of the drug under each contract and order from the supplier with the lowest price at the time the drug is ordered.

One facility, Los Lunas, has a contract with a vendor for pharmacy services, presumably to fill individual resident prescriptions.[7] It's vendor, Rx Innovations, is a New Mexico company.

Recommendations for IPPC Facilities

Recommended Step 1:

Review and benchmark the three pharmacy services vendors used by Corrections, Juvenile Justice and Los Lunas in the Department of Health.

Recommended Step 2:

It could be worthwhile to compare prices/discounts for the highest cost/highest spend products in the Department of Corrections, Juvenile Justice, and Los Lunas with the Department of Health Cardinal contract.

If there is an opportunity for savings, it may be possible for Corrections to stock the high cost products on site from Cardinal. There may be savings for Juvenile Justice as well. It is not clear that Los Lunas can stock and dispense because it is a supported living facility rather than a residential treatment facility. Los Lunas should benchmark its contract with the pharmacy services contracts of the other agencies.

Additionally, agencies with contract pharmacy services can spot check their actual billed drug ingredient costs for a sample of drugs against the federal National Average Drug Acquisition Cost (NADAC) database, which is a federal, public database that surveys pharmacies for what they had to pay to stock different drugs. The NADAC is not a 100 percent participation survey or a rigorous statistical sample survey. It is thought to have more participation from pharmacies that have higher

[7] The author did not interview staff at Los Lunas owing to scheduling difficulties. The interpretation of Los Lunas pharmacy services is based on research, not staff interviews.

acquisition costs, rather than participation of large chain pharmacies, which have lower acquisition costs. It could be important to know that facilities are not paying more than NADAC prices.

Recommended Step 3:

Determine if access to 340B drug supply and pricing is maximized for State facilities. Are all potentially eligible clinics enrolled? Is there an approach that moves Department of Health or Department of Correction facility residents to 340B facilities for treatment? Several states have negotiated agreements between their departments of corrections and state university medical systems that are 340B entities. The agreements provide that inmates are treated by those 340B eligible medical systems. Corrections can then access lower cost drugs as a result of the agreement. Other states have extended health department 340B clinic status to corrections facilities.

Additional, General Recommendations for IPPC Consideration

Recommendation 1:

New Mexico may determine that creating a statewide government office of prescription drug contracting and procurement could help the State meet goals and operational changes recommended by the IPPC. California has such an office that handles both procurement for state entities and helps to manage state payer pharmacy benefit management contracting. Governor Newsom expanded the role and remit of this office at the start of 2019 to potentially include private sector payers in California public program negotiations. He expanded the role again in early January 2020 to have the state contract for the manufacture of generic prescription drugs that will be available statewide – so that a state-manufactured generic replaces the industry versions at a lower cost (or the result could be that existing generic companies will compete with California on price to remain in the market).

Massachusetts and a few other states have offices that are more limited than the office in California; they order and supply drugs for certain state and local government purchasers such as state hospitals and law enforcement.

Recommendation 2:

Manufacturer price concessions (whether through a PBM or not) are generally based on the ability of the entity on the other side of the table to ensure that it can move market share to the manufacturer's product and away from competitor products. The payer/purchaser negotiating leverage generally grows as the number of covered lives grows. Creating a large purchasing pool should beneficial. In order to move market share, the participants in the purchasing pool should agree that they will "prefer" coverage of one product over a competitor product. Unified purchase and coverage decisions among different payers and purchasers can be difficult (in no small part because of the existing PBM or other vendor contracts each purchaser or payer already has in place). The extent to which state payers and purchasers can agree to 'prefer' specific drugs, may improve the level of price concession. The actual financial benefit of this pooled negotiation will vary by agency or payer based on what that payer or agency already achieves in the market.

Recommendation 3:

Create (or contract for) a high-risk insurance pool that addresses coverage of high cost, rare condition treatments (i.e. gene therapies) for which payers are struggling to finance. Participating payers (which could be public and private) would pay a per person/per month amount into a pool that covers and finances the entire costs of gene therapy (or other agreed-to treatments that would be covered through the pool). Express Scripts has offered this type of high-cost, stand-alone insurance pool for coverage of gene therapies. The Express Scripts offer extends to self-insured employer plans that use Cigna has their benefits administrator.

Recommendation 4:

Incentivize plan enrollees to obtain prescribed medications from Mexico or Canada.

The Utah public employees plan provides incentives for enrollees to obtain certain prescription medications from Mexico and Canada. The health plan will pay travel costs when necessary. The program, which began with incentives to obtain certain medical procedures in Mexico, has been in place for several years. The ex-U.S. pharmacy services is a newer component of the program. The State

program has a relationship with a specific facility in Mexico where state employees obtain their medication. Elimination of prescription cost sharing, providing paid travel and additional paid leave are some of the incentives that Utah offers employees who avail themselves of ex-U.S. medical services and pharmacy.

About 500 local governments and private employers incentivize their enrollees to obtain prescription medications from the Canadian company, CanaRx. It has been a safe and cost-savings program for employers since early in the 2000's. There is no need for pooling covered lives to participate in this service. Federal law does not permit importation of drugs from other countries (even though most of our drugs are now made overseas). However, FDA decided several years ago that it would not enforce the law when drugs are imported for personal use – which is defined as no more than a 90-day supply. See a brief history/explanation of importation of drugs into the US with a discussion of CanaRx.

How to Include New Mexico Commercial and Self-Insured Payers

Recommendation 1:

Include private sector payers in a multi-agency consolidated PBM procurement.

Recommendation 2:

Create a public/private purchasing organization to negotiate directly with manufacturers or other suppliers as appropriate for high-cost or high-volume drugs, strengthened by a commitment among participants to do either sole source contracting or agree to 'prefer' negotiated drugs in their formularies. This could be a physical procurement of drugs for distribution throughout the state, or a rebate-based program. It could include just payers, just purchasers, or both.

Recommendation 3:

Include private sector payers in the high cost treatment risk pool as discussed in the previous section.

Recommendation 4:

Examine the feasibility and desirability of creating a Prescription Drug Affordability Board. Several states are thinking about this in this legislative session. Two states enacted early versions of such a board in 2019. The model act that states are using would create a Board, like the public service commission (which operate in every state). The board would establish upper payment limits on certain high cost drugs. The upper payment limit would establish a ceiling on the cost of a drug that applies to all financial transactions in the state for the drug with the upper payment limit.

Recommendation 5:

Participate in any new effort to develop non-profit manufacturing of generic prescription drugs.

The Governor of California just announced his intent that the State contract for the manufacture of generic drugs. While the details are still under development, the state could supply the product to the entire state supply chain. The initiative would result in the complete price transparency of state manufactured drugs; price transparency is essential to changing the biopharmaceutical market in the U.S. There are no patent or trade secret law impediments to doing this because the initiative is limited to off-patent drugs.

Several hospitals came together several years ago with the intent to put together enough capital to build a manufacturing plant for generic drugs important for inpatient hospital care that are routinely in shortage status (as defined by the Food and Drug Administration). Ultimately, what is now known as CivicaRx, decided to simply pay an existing drug generic manufacturing facility to produce needed inpatient generic drugs for purchase by the members of CivicaRx. CivicaRx is essentially a member-owned, non-profit private label drug distributor and intends to become a manufacturer of off-patent products in the future.

Most recently, 18 Blues plans announced their intent to become a subsidiary of CivicaRx for the purpose of manufacturing off-patent drugs that can be dispensed in outpatient settings.

While it is not common knowledge, Massachusetts and Michigan Departments of Health operated vaccine manufacturing facilities for production of DTP, other vaccines and biologic treatments. The Massachusetts laboratory is still in operation, the Michigan laboratory was sold to a private company in 1998. The Mass Biologics Laboratory is more of a public-private partnership model today but is still state owned and non-profit.

In terms of undertaking similar initiatives for products like off-patent insulin, it may be more economical for several smaller states to come together to create a manufacturing enterprise, if not participate in some of the nascent initiatives.

Conclusion

There is more to explore as the IPPC begins the hard work of identifying possible approaches to prescription drug cost containment. The work is not easy – creating a common understanding of how things work, a common terminology to describe both old and new processes, and a willingness to "go big" in member thinking is challenging. The challenge also includes thinking about how the approaches under consideration in IPPC could complement or dovetail similar work in other states and multi-state entities. The IPPC should be watching the evolving innovations of other states as well.

But to start, it is important to fully understand the processes and contracting arrangements of each IPPC member today.

Sources

New Mexico data in this report came from documents available on the IPPC website:

https://www.generalservices.state.nm.us/uploads/files/OOS/IPPC/Pharma_info_for_IPPC.pdf

https://www.generalservices.state.nm.us/uploads/files/OOS/IPPC/IBACAgencyRxPlanCostCompare_FY19.pdf

https://www.generalservices.state.nm.us/uploads/files/OOS/IPPC/Pharma_info_for_IPPC-9_24_19.pdf

Appendix A
340B program in New Mexico

The federal 340B program began after the Medicaid Drug Rebate Program started in 1990. 340B was a response to the loss of discounts voluntarily provided by drug manufacturers to safety net providers all over the country. The voluntary efforts ended when the Medicaid drug rebate program was created.

Because of the loss of discounts, Congress created the 340B program (named for the section of federal public health law to which it was written). The program requires that manufacturers provide Medicaid-level pricing for *outpatient* drugs dispensed or administered by eligible and enrolled entities. Manufacturer price concessions are exempt from Medicaid best price requirements which means that 340B may sometimes get a better price than the discount provided to Medicaid.

The program has grown considerably over the years both organically and in response to expansions of federal law. The program now captures in about $24 billion in annual drug sales. The federal 340B data base lists about 47,000 participating 340B entities and the Government Accountability Office reported about 20,000 participating contract pharmacies several years ago already.[8]

In New Mexico, the federal 340B database lists about 35 340B-registered entities. The 340B contract pharmacies associated with the 340B entities in New Mexico is in the hundreds although each pharmacy contracts with several different 340B entities in the State, so the actual number of contract pharmacies in New Mexico is lower. State 340B entities also contract with several out of state pharmacies that supply specialty medications. Participating New Mexico entities include public health clinics that provide family planning medicines and other eligible services, as well as hospitals such as St. Vincent and Trigg Memorial.

There are ten New Mexico hospitals in the 340B program because they have a special federal designation of "disproportionate share hospital" (DSH). These hospitals, like their peers around the country, leverage the program to generate revenue. These entities may have up to 70 retail community pharmacy partners and most, if not all, of their outpatient clinics are enrolled. Additionally, DSH drug purchases for inpatient use are exempt from the federal Medicaid best price requirements, which here again means that these hospitals can leverage significant discounts, perhaps better than federal Medicaid or 340B price concessions.

Like Medicaid, 340B discounts are confidential by law so that 340B entities cannot reveal the discounts. Until recently, 340B entities did not know the federal ceiling price and could not know if they were being overcharged. The federal administering agency, the Health Resources and Services Administration

[8] The definition of "covered entities" includes six categories of hospitals: disproportionate share hospitals (DSHs), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals (CAHs). Hospitals in each of the categories must be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. In addition, except for CAHs, hospitals must meet payer-mix criteria related to the Medicare DSH program. There are also ten categories of non-hospital covered entities that are eligible based on receiving federal funding. They include federally qualified health centers (FQHCs); FQHC "look-alikes"; state-operated AIDS drug assistance programs; the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs; tuberculosis clinics; black lung clinics; Title X family planning clinics; sexually transmitted disease clinics; hemophilia treatment centers; Urban Indian clinics; and Native Hawaiian health centers. https://www.340bhealth.org/members/340b-program/overview/ accessed 1/10/2020.

(HRSA), now posts the ceiling prices for each drug. The list is accessible only to 340B entities. Entities can access that list to ensure they are not overpaying for 340B drugs (or overbilling Medicaid programs).

If the IPPC wants to consider 340B policies, it would be useful for it to understand the operational mechanics of the program. Knowing whether 340B price concessions are provided via on-invoice discounts or via back-end rebates could be important to policy considerations. The program has grown so large that the operations are complex, and the operational mechanics of the system could influence how the IPPC thinks about the program.

Appendix B
Glossary of Key Pharmaceutical Market Terms

Drug Product Terminology

Small Molecule Drugs: Drugs with an active chemical ingredient that is not live, but chemically synthesized and typically are taken orally or topically, such as capsules, tablets, powders, ointments, and sprays.

Brands: Also referred to "small molecule drugs," brand drugs require original research and development for FDA licensure (also called "FDA approval"). They are approved (or licensed) under a New Drug Application (NDA). They are patent protected for 20 years total (which usually includes years clinical research before the drug is approved, or licensed). They are still referred to as brands even after the patent has expired (which distinguishes these drugs from generics). A brand can be 'first in class" if it is a new chemical entity or new mechanism of action. It is a "me too drug" if it is not first in class. The definition of "me too" varies – different chemical composition, different mechanism of action. The drug is quite similar but different enough to get a patent.

Generic: Small molecule products that are demonstrated to be clinically equivalent to a branded product (e.g., same active ingredient and route of administration, same mechanism of action). Generics do not require original research for FDA approval. Generics come to market only after the patent has expired on the brand product. Licensed under an Abbreviated New Drug Application (ANDA) by the FDA.

Large Molecule Drugs: Commonly referred to as "biologics" and "biosimilars." They contain live active ingredients and are generally infused or injected, and otherwise not taken orally or topically.

Biologics: Also referred to as "large molecule drugs," biologics are therapeutic treatments made from living cells, such as viruses, serums, toxins, antitoxins, blood products, allergens or proteins. Biologics are typically not taken orally and are licensed under a Biologic License Application by the Food and Drug Administration (FDA). Insulins and vaccines are biologics even though they have been on the market for years before the term 'biologics' was developed and years before the new biologics approval pathway was created.

Biosimilars: Therapeutic biologic treatment that is "highly similar" to a previously approved biologic for which patent and data exclusivity have expired. Because biologics are made from living cells, biosimilars are not absolutely equivalent to the original drug (like a generic drug would be) but it would have "no clinically meaningful" difference from the original biologic. Biologics and biosimilars are thought to be 'interchangeable' like the way "brand" and "generic" drugs are clinically interchangeable.

Data Exclusivity: An additional protection afforded to biologics where the clinical trial data is not public for 12 years from licensure, which means that data needed to create a competitive biosimilar of the product may remain a trade secret for longer than the actual biologic product patent.

Orphan Disease/Orphan Drugs: Small or large molecule products that treat a disease that affects fewer than 200,000 people. Manufacturers of orphan drugs get particular benefits from being licensed as an orphan drug, such as tax credits and certain market exclusivity, among other benefits. An orphan drug can be approved to treat more than one disease, only one of which must be an orphan disease.

Pipeline Drugs: Small or large molecule drugs that are still under development by a manufacturer. Information about these drugs is public to a certain degree on a manufacturer's website.

In-Line or Post-Market Drugs: Products that are FDA-approved and available for sale in the market.

Off Patent/Single-Source Drug: Applies when a brand has lost its patent but there is only one manufacturer that continues to produce the drug. Applies to small molecule drugs.

Multi-Source Drugs: This is an alternative term for generics where there is more than one manufacturer of the brand drug that has lost its patent protection.

Retail Drugs: Drugs that are publicly available, typically through a retail drugstore. Includes prescription and over the counter (non-prescription) drugs. Retail drugs are distinct from drugs when they are available only at the wholesale class of trade or drugs that are only available through closed specialty pharmacy systems where the public cannot just directly obtain the drugs. Retail drugs are found at retail pharmacies and mail order pharmacies and are usually billed on a pharmacy claim.

Specialty Drugs: Brands, generics, biologics or biosimilars that are costly, require special handling such as freezing or cold storage, and may necessitate special case management services for patients. Specialty drugs are those that are suitable for Limited Distribution (see below). Often, specialty drugs are only defined by their cost. For instance, specialty drugs in the Medicare Part D program are classified as those that have a cost over a certain threshold, currently $670/month (2018) and indexed annually.

Limited Distribution Drugs: Drugs for which distribution is tightly controlled by manufacturers through specific pharmacies or wholesalers. These are generally biologic drugs and specialty drugs that require special handling or have complex regimens or require patient management. Limited distribution of biologics can make it difficult for potential competitors to access the product and conduct studies needed to develop biosimilars. These drugs are synonymous with Specialty Drugs (see above).

Over the Counter (OTC) Drugs: Available to the public without a prescription. Almost OTC drugs are approved by the FDA, unless they have been on the market since before modern FDA approval processes were established in the early 1960's.

Drug Supply/Distribution

Specialty Pharmacies/Limited Distribution: These organizations may or may not take ownership of the drug product. They contract directly with drug manufacturers for limited distribution of specialty drugs. Specialty pharmacy can deliver 'just in time' products by working with treating providers to supply the appropriate drug in time for a patient visit at the location where the drug will be used. They are not retail/not open to the public.

Wholesalers: Wholesalers purchase very large quantities of drugs directly from manufacturers. They are the start of the general distribution "supply chain" and store large quantities of drug products in regulated warehouses that

are state-inspected and licensed. Smaller wholesalers include regional pharmacies that ship locally to other dispensing sites. States license and regulate wholesalers and small distributers operating in-state. The 'wholesale' class of trade is not open to the public. The average price at which a manufacturer sells its drug to wholesalers is the "Wholesale Acquisition Price" (WAC).

Retail Pharmacies: Retail pharmacies are open to the public to dispense/sell retail drugs (brand, generic, and OTC). Retail pharmacies can be chains (such as CVS, Walgreens, or RiteAid) or small regional or local independent businesses.

Drug Development Terminology

Drug Efficacy: The extent to which the drug performs as expected in a clinical trial (highly controlled environment). FDA approvals consider drug efficacy.

Drug Effectiveness: The treatment effect of a drug in the 'real world,' or uncontrolled, market environment.

Bench Science: Scientific work on the basic molecule/chemical. This is typically publicly funded and conducted at research universities. Promising molecules are bought by manufacturers for "commercialization." The research entities typically sell the molecule for a payment and future royalties.

Commercialization: The scientific work a drug manufacturer undertakes to move a drug from a promising molecule to a licensed product. Only 10-12 molecules out of 100 research endeavors will make it through the entire process and gain FDA approval. Commercialization involves clinical trials.

Clinical Trial Drug Development: A scientific process (and successful results) is required for FDA approval of brand and biologic drugs.

- *Phase I* – Tests for safety in a small number of human volunteer subjects. Lasts several months.
- *Phase II* – Tests for efficacy. Randomized trial design. Several hundred volunteer subjects. Lasts several years
- *Phase III*—Large scale human testing of efficacy and safety in a (typically) much larger group of volunteer subjects. Randomized trial design. Can last several years.

Randomized Clinical Trials (RCT): RCTs are the gold standard for drug development and drug approval in the US and other countries. RCTs have a control group arm and an experimental arm. Importantly, subjects are randomly assigned to one arm or the other to control for any possible experimental bias.

Breakthrough Drugs/Expedited Approval Pathways: The FDA has authority to grant 'fast track' approval processes for certain types of drugs as authorized in federal law. Breakthrough drugs are assessed to be clinically important for diseases with no or few treatment options, or a thought to be a major treatment improvement. There are other fast track classes as well. Expedited approval reduces the scientific standard – fewer human subjects, shorter testing periods, clinical outcomes measures that are proxies for actual outcomes or treatment effects.

Drug Payment Administrative Organizations

Group Purchasing Organizations (GPOs): GPOs represent groups of drug purchasers, such as hospitals and health systems. A GPO negotiates with manufacturers on behalf of its clients for either up-front, on-invoice discounts or back-end rebates. Importantly, GPOs do not take ownership of a drug; they are

not part of the supply chain. GPOs essentially negotiate a purchase-order from which members of the buying group can purchase in whatever quantities needed. Wholesalers supplying to GPO members typically provide the drug at the discounted price on the invoice and then receive a rebate (called a chargeback) from the manufacturer of the drug after the fact. GPOs may provide additional client administrative services as well.

Pharmacy Benefit Managers (PBMs): PBMs manage some or all the pharmacy benefit for commercial and other health plans such as large employers, union trusts, and government agencies. These services can include formulary design, cost sharing and tiers, pharmacist networks and contracts, price concession negotiation with manufacturers. PBMs pay the pharmacies that dispense the drug and then get reimbursed from the health plan. PBMs may own mail order pharmacies and/or specialty pharmacies and may have business relationships with retail pharmacy chains (for example, CVS/CVS Caremark).

Pharmacy Services Administration Organizations (PSAOs): PSAOs serve pharmacies in the same fashion as a GPO and take on other administrative functions for member pharmacies, including contracting with PBMs for pharmacy payment terms and conditions, as well as audit protocols, reconciliation and appeals processes, fees and other reimbursement methodologies.

Purchasers: Entities that purchase (and own) drugs for dispensing or other administration.

Payers: Typically, are health plans – entities that reimburse purchasers (pharmacies, hospitals, physicians for instance) for the drugs they bought then dispensed or administered to payer enrollees.

Pricing Terminology

Wholesale Acquisition Cost/List Price (WAC): WAC (or list price) is the average price at which a manufacturer sells a drug product to the wholesale class of trade. This is a published price and is generally considered the 'list price." The WAC is the basis for supply chain product sales and purchases. Medicare law conflated WAC and list price several years ago. Technically (without regard to Medicare law) WAC is lower than list price. Technically WAC includes a discount from list price (if any) but the Medicare law changed the definitions. So, it can be confusing when WAC is used to mean different things.

Average Wholesale Price (AWP): AWP is the price at which wholesalers sell drugs to the retail class of trade. For brand medicines, this price is almost always higher than the WAC and represents the starting point for contract negotiations for medicines between payers and pharmacies/providers. AWP serves as an important pricing benchmark for payers because underlying data is continuously current and publicly available and represents the average cost for a drug purchased at wholesale and published for public knowledge. It is available through commercial pricing publications.

Actual Acquisition Cost (AAC): The net cost of a drug paid by a pharmacy. AAC varies with the size of container purchased (e.g., ten bottles of 100 tablets typically costs more than one bottle of 1,000 tablets) and the source of purchase (manufacturer, wholesaler or regional distributor). A drug's AAC includes discounts, rebates, and other adjustments, but excludes dispensing fees – which are paid

separately. Since it is not usually possible to know the AAC of each drug for every participating pharmacy, the AAC is typically estimated using national pricing data sources.

Average Manufacturer Price (AMP): AMP is a Medicaid-required calculation from manufacturers. It captures the average price at which manufacturers sell a product to the wholesale and retail classes of trade. It excludes all price discounts and other price concessions. The AMP is the basis of the Medicaid rebate calculation.

Average Sales Price (ASP): ASP is a Medicare Part B reimbursement term. It is the amount Medicare will reimburse a provider who has dispensed a Medicare Part B drug. ASP is the weighted average manufacturer net price for a product in the market. This applies to multi-source drugs and patented products. Medicare reimburses physicians ASP+6% for Part B drugs.

Maximum Allowable Cost/Federal Upper Limit (MAC/FUL): Payment limit methods that apply only to multi-source drugs (including off-patent brand drugs that have generic competitors). MAC/FUL is the average price among all the multi-source drugs in a group. The frequency the MAC/FUL is recalculated is at the discretion of the payer. The multi-source drugs to which a MAC is applied is also at the discretion of the payer. MAC is term used by commercial payers, FUL is used by CMS for the Medicaid program.

National Average Drug Acquisition Cost (NADAC): NADAC is the average price paid by the retail class of trade. It is a version of AWP created by CMS to provide more accurate pharmacy acquisition cost information for purposes of payer reimbursement. AAC, AWP, NADAC all generally attempt to capture the price in the pharmacy purchase transaction.

Rx Financial Transaction Terms

Price Concession*:* Any and all types of reductions in cost at any point in the supply chain and between any entities within the supply chain, such as manufacturers, wholesalers/distributors, pharmacies, PBMs/insurers.

Discount: A price concession that typically is an up-front, “on-invoice” price reduction, like the familiar retail sales discounts common in consumer experience.

Rebate: A price concession that occurs separately from, and after, the actual purchase transaction. Example -- A manufacturer provides a rebate (a percentage off the WAC or list price) after the insurer/PBM has paid the pharmacy for a drug dispensed to a health plan enrollee. The amount of any rebate is: 1) proprietary; 2) typically dependent on volume of drug dispensed or placement of the drug on the insurer’s formulary; and 3) paid periodically (i.e. quarterly or bi-annually) for all transactions that occurred during that period of time.

Price versus Cost: In drug policy it is helpful to distinguish between “price,” which is what the manufacturer establishes and “cost” which is the financial effect on the purchaser. Payer costs reflect any discounts or rebates if available that affected the cost of the drug for the purchasers.

Charge Back: A wholesaler will bill a manufacturer the difference between what the wholesaler paid to purchase the drug, and the price at which the wholesaler was able to sell the drug when the manufacturer has contracted directly for discounts with entities that purchase from the wholesaler. The wholesaler fulfills the manufacturers price concession for the manufacturer and then is 'made whole' by the manufacturer.

Fees: Different parts of the drug supply and financing chains have certain fees. Pharmacists have "professional fees" or "dispensing fees." PBMs collect fees for administrative services provided to their clients and manufacturers. Wholesalers and distributors may collect fees from manufacturers for certain services provided. Fees may be a percentage of price/charges or a set fee amount, such as pharmacy dispensing or professional fees.

Appendix C

State-Based Resources Available to the IPPC

National Governors Association (NGA.org)

NGA has funding to staff a collaborative of six states working on new inter-agency purchasing strategies. The learnings from the collaborative will be available to other states.

The SMART D Project

The State Medicaid Alternative Reimbursement and Purchasing Test for High Cost Drugs (SMART D) is a project of the Center for Evidence Based Policy at the Oregon Health and Sciences University. It has funding to develop tools to help states embark on multi-agency payment and procurement of prescription drugs. The project is nascent and there are no publicly available resources yet (as of 2/2020). They have other resources for alternative payment models in Medicaid.

The NW Consortium and the Minnesota Multistate Contracting Alliance for Pharmaceuticals (now called MMCAP-Infuse)

The NW Consortium and MMCAP-Infuse are *state-run* services that assist state agencies and entities with pharmaceutical costs. The NW Consortium is administered by Oregon and Washington; it operates primarily as a pharmacy benefits manager for state programs, private sector employers, and commercial health plans. It provides other services such as drug discount cards.

The MMCAP-Infuse helps state non-profit entities procure discounted pharmaceutical and other medical supplies. It has an increasingly detailed pricing approach depending on individual member willingness to 'prefer' certain products. Like the NW Consortium, MMCAP-Infuse offers a range of other services to state entities and agencies such as contract pharmacy services.

These two organizations are complimentary in that one addresses the needs of health plans (payers) and the other addresses the needs of direct purchasers (state hospitals, corrections facilities, public health clinics). Both these organizations have expressed interesting in growing their memberships and diversifying their service offerings.

The National Academy for State Health Policy (NASHP.org)

NASHP has a webpage with resources for states looking for policy options to constrain prescription drug costs.

The National Conference of State Legislatures (NCSL.org)

NCSL has resources about state prescription drug cost policies and legislation.

Appendix D

IPPC Payers and Purchasers

Payers

Government Services Risk Management Division

Albuquerque Public Schools

Retiree Health Care Authority

New Mexico Public School Insurance Authority

University of New Mexico

University of New Mexico Health System

Presbyterian Health Plan (Medicaid)

Western Sky Community Care (Medicaid)

Blue Cross Blue Shield New Mexico (Medicaid)

Medicaid Fee for Service

Purchasers

New Mexico Department of Corrections

New Mexico Children Youth and Families Department

New Mexico Department of Health

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