Implementing Limited-Reach UPLs (revised)

Upper payment limits will work best if the UPL applies to all purchases, payments, billings, and reimbursements statewide. Ideally, the entire state supply of the UPL prescription product comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers. The UPL product is then available to everyone, including people without insurance. The wholesaler negotiates with the manufacturer to buy the product that does not exceed the upper payment limit (presumably, there will be room for a wholesaler discount). Sales and acquisition costs operate in the same way as they always have where the supply chain makes some margin (profit) on the product along the way and the acquisition cost to the pharmacy/other providers should not be more than payer reimbursement formulas. In a statewide scenario, the payer product reimbursement is the UPL (professional fees are not part of the UPL).

Government-only UPL

UPL through the supply chain: If a PDAB UPL authority extends solely to state and local government health plans and enrollees, and direct purchasers, as it will in Maryland initially, the option of moving a government-only UPL product through the supply chain using the UPL may be complex. Most importantly, manufacturers will need to know that their UPL products are only being used for government plan enrollees and state/local facilities and not diverted to other consumers who might be billed above the UPL with a drug acquired at the UPL discount. Monitoring for diversion will be complex and retrospective.

Dedicated wholesaler: Contracting with a wholesaler dedicated to the distribution of UPL drugs may be an option. Manufacturers can collaborate with the dedicated wholesaler on distribution channels that satisfy their concerns about diversion. A dedicated wholesaler option for handling and monitoring distribution and avoiding diversion may become an efficient approach once federal track and trace is fully implemented and drugs are serialized to the package level. This approach may be most efficient for direct purchasers even in a statewide UPL approach.

Of note, McKesson operates the federal Vaccine for Children program – vaccine purchasing, warehousing, and order fulfillment. The current VFC model evolved from a depot-style bulk delivery and state distribution of childhood vaccine to participating physicians to the more efficient model we have today. Pediatricians and other private and public sector participating providers order directly from McKesson to restock childhood VFC vaccines at no cost which are then provided free to low-income children. The program most likely has operational and administrative policies and procedures that can inform a limited-reach UPL programs including diversion. The VFC model might also be appropriate for state and local government direct purchasers such as hospitals, public health clinics, and depending on the product, and first responders..

Mail Order UPL Rx: Mail order arrangements via plans' PBMs could be considered because it offers less opportunity for diversion and the amount of UPL product required can be estimated in advance from payer data for purposes of purchasing from the manufacturer or a wholesaler who would get a chargeback[1] from the manufacturer.

[1] When a wholesaler buys from a manufacturer at a price and fulfills manufacturer discount commitments to dispensing or administering providers, the wholesaler is reimbursed for the difference -- made whole for the financial loss on the discount sale.

Implementing Limited-Reach UPLs (revised)

UPL as rebate to payer: If the UPL is limited to state and local government payers, as in the first years of the Maryland program, the UPL agreement could be executed through the government employee plans' PBM contracts. (Another approach would be needed for direct government purchasers). This is perhaps the simplest solution for government payers at the start of the program because the rebate system is already entrenched in manufacturer and payer operations.

The UPL product would come into the state at regular market prices. The drug is dispensed or administered, government plans are billed at market prices and plans reimburse at market prices. Then plans bill the manufacturer for rebates which bring the plans' net costs down to the UPL.

There is no requirement in Maryland law that government health plans assure that the consumer cost sharing is based on the UPL.[2] Government payers should consider using the net cost as the basis for consumer cost sharing for multiple reasons, the first of which is to deliver on the promise of the UPL to the consumer. The second reason is that the manufacturer should get reputational credit with consumers once the drug is more affordable.

UPL at the point of consumer service: If the UPL is to get to the consumer within the rebate approach discussed above, government payers will use their pharmacy network information systems to list a specific cost sharing amount for the product that is based on the UPL. Because the deductible or coinsurance cost share amount is less that it would be in the absence of a UPL, the pharmacy/other provider bills the government plan more than it would have billed in the absence of a UPL. (Pharmacies bill product acquisition cost minus consumer cost sharing collected by the pharmacist). In this situation, the plan reimburses the pharmacy more than it would have in the absence of the UPL-related cost sharing reductions, but the manufacturer rebate will net the plan cost to no more than the UPL . This would be quite like the system created at the start of the Medicare Part D program to operationalize mandatory manufacturer contribution to drug costs for patients in the coverage gap. (The coverage gap has since been eliminated.)

Part D plans used pharmacy billing and IT systems to clarify what the patient is charged when in the coverage gap. Pharmacy billed the Part D plan acquisition cost (market price) and Part D plan reimbursed pharmacy then bills the manufacturer, on a quarterly or other basis, for the manufacturer's share of the cost of the drug in the coverage cap – per federal law. The plan has verified that the drug goes only to the eligible person. This system was not designed to work with Part B or beneficiaries not enrolled in Parts D or C (managed care).

Added since version 1: As of June 2023, the newest CMS guidance signals a significantly different approach than the early Part D operation. The new approach can address both retail and physician administered products subject to a negotiated price (Maximum Fair Price, MFP). It could be a fairly heavy administrative touch but would get the MFP to the point of service – which is required by law as CMS points out in the newest guidance. Pharmacy/other providers purchase product at market, but bill Medicare at the MFP then Medicare reimburses at the MFP. While the relationship of the vendor to pharmacies and providers is not specified yet, it seems likely that the pharmacy/provider will notify the vendor of the MFP dispensing using a claim form that includes billing for a refund[3] for the difference

[2] This is only an issue with a rebate system where the drug is transacted at market prices.

[3] The term "refund" is not CMS terminology but is used here to distinguish between rebates and this process of ensuring the pharmacy/provider is not under reimbursed relative to acquisition costs.

between product acquisition cost and the MFP. Manufacturers will not be required to refund to 340B entities who purchase at a price lower than the MFP (and the price formula is federal law). The vendor verifies the MFP product was given to an eligible Medicare enrollee (those enrolled in Part B and Part D or Part C), refunds the difference between the provider's product acquisition cost and Medicare reimbursement at the MFP. The vendor then bills the manufacturer of the drug for the vendor's outlay of the refund.[4] CMS suggests interest in setting one national refund formula such as WAC minus MFP, which would simplify the process considerably. It is not clear whether this formula might sometimes cost manufacturers more than an individually calculated refund or might sometimes refund less to providers. The vendor will not pay a refund to a provider that is a 340B entity, unless the 340B price is higher than the MFP (which is unlikely). However, the vendor/CMS/federal 340B agency will have to determine how to identify 340B dispensed drugs.[5]

Something like this new CMS proposal may work for a state and local government only UPL, although it is more complicated than the straight rebate model. It might be an alternative to the dedicated wholesaler approach for government entities that purchase/stock drugs. 340B double discounts will be an issue for Maryland under this model as most 340B entities are government providers/clinics/hospitals.

Statewide with Segmented Market UPL

If the UPL is limited to most but not all market segments and most consumers statewide, the situation is perhaps more complex than a government-only UPL scenario. This may be the situation in Colorado.

The Colorado law requires that a UPL operate statewide to *all purchases and payer reimbursements* with an opt-out for self-insured plans. States cannot regulate Medicare benefits, payments and of course Medicare plans and fee for service cannot be required to pay at the UPL, but state-licensed providers are required to participate. The law was intended to cover all Coloradans, including the uninsured.

One way to interpret the Colorado final regulation is that any consumer – regardless of insurer or insured status—must be able to obtain the UPL cost drug at the point of service. Therefore, the UPL drug may have to be available to all pharmacies and all other administering providers. In this scenario, it is not clear if providers can bill Medicare and non-participating ERISA plans more than the UPL. Non-participating plans can certainly reimburse more than the UPL.

All consumer/not all payers approach: The dedicated wholesaler approach discussed in the previous section might be the best approach to operationalize the supply of UPL product in this scenario. The UPL drug comes into the state through the supply chain at or below the UPL from the dedicated wholesaler. In this scenario, in-state pharmacies and providers will only buy and stock the drug at or below the UPL -- and sell to all consumers at or below the UPL. The wholesaler can support the government owned, direct

[4] This last administrative process is similar to PBMs billing their health plan clients for pharmacy claims payment outlays.

[5] On the standard pharmacy claim, there is a field to note if the Rx was purchased at 340B price. It is seldom used and difficult to enforce. There is no such field on an outpatient provider or clinic claim form and infused, injected, IV products are 340B when used in outpatient settings. There is a federal database of all 340B participating entities which can be queried by state. The complication is the use of thousands of contract pharmacies like Walgreens who are contract pharmacies for *many* different 340B entities.

purchasers as well. Note that the insurer/PBM rebate system discussed in the previous section will not be sufficient to manage consumer UPL access to enrollees of non-participating plans and the uninsured.

Not all consumers/not all payers approach: If the final Colorado regulation means that enrollees of non-participating ERISA and Medicare D and B enrollees do not have access to the UPL of a drug, then the supply chain becomes more complex. Pharmacies and providers will have to rely on the insurer pharmacy information systems to know what to charge the consumer and the plan. Presumably, individual physicians/clinics will not apply the UPL to Medicare consumers and will bill Medicare at higher Medicare rates.

A dedicated mail order service, used by all participating plans and the uninsured, could be a supply option for the approach. It minimizes opportunities for diversions and maintains access for the uninsured. A mail order service may require a chargeback/rebate system that operates between mail order companies that dispense in multiple states and manufacturers to ensure the manufacturer has a line of sight into the mail order company's use of physical product sold into Colorado. However, brick and mortar, in-state pharmacies may have business concerns about a mail order system.

Other issues when not all payers participate: The Colorado state regulation and policy seem to allow a provider to bill a non-participating ERISA plan (or Medicare) more than UPL. However, if the non-participating ERISA plan is aware of the statewide UPL, it could be unlikely the plan would choose to pay more than the publicly known pharmacy product acquisition cost. As a matter of Medicare rules, Medicare Part B and possibly Part D, would be obligated to pay no more than the product acquisition cost (which is typically done using a formula that estimates what the acquisition cost is for the pharmacy or provider). If the actual acquisition cost for every provider is public, Medicare intermediaries and plans may be obligated to use the UPL for reimbursement.

Manufacturers may have an interest in how "non-participating" ERISA plans or Medicare are reimbursing providers/pharmacies. The manufacturer will want to guard against double price concessions. Double concessions would occur if the manufacturer had a rebate agreement with a Part D plan or a non-participating employer plan based on volume and/or formulary placement *and* the manufacturer supplies product within the State at or below the UPL. Unlike provider billing of plans, plan provider payments may be a matter of State interest if manufacturers cannot obtain the data but need the data to understand exactly what is happening with UPL product and reimbursements for UPL products.

Added since version 1: The new CMS guidance on operationalizing the Medicare negotiated price, discussed in the previous section, may also be suitable for Colorado's situation. It could address UPL access for the uninsured and it could address some, if not all, manufacturer concerns with diversion. If it is going to be the official Medicare process, Colorado's pharmacies and providers will be familiar with it and any needed modifications to universal claims forms will be made. The cost to Colorado to build on the Medicare system may be less than it would have been to create it de novo.