By Electronic Submission

January 16, 2018

Ms. Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, MD 21244

RE: CMS-4182-P—Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Dear Administrator Verma:

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to comment on the Proposed Rule entitled "Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (the "2019 Proposed Rule"), which was published in the *Federal Register* on November 28, 2017.[1]

NCPA represents the pharmacist owners, managers, and employees of more than 22,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines. Independent pharmacists are small business entrepreneurs and multifaceted health care providers who represent a vital part of the United States' health care delivery system.

We hope the Centers for Medicare & Medicaid Services ("CMS") finds our recommendations and comments helpful as it finalizes the 2019 Proposed Rule. We have divided our recommendations and comments by topic and submitted supporting documents attached to these comments.

[1] 82 Fed. Reg. 56, 336 (proposed Nov. 28, 2017).

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Price Concessions to Drug Prices at the Point-of-Sale[2]

As part of the 2019 Proposed Rule, CMS has solicited information relating to a proposal that Medicare Part D Plan Sponsors ("Sponsors") be required to include all pharmacy price concessions and a minimum percentage of manufacturers rebates in the drug's "negotiated price" at the point-of-sale rather than accounting for retrospective pharmacy price concessions and manufacturer rebates as "Direct and Indirect Remuneration" ("DIR") long after completion of the plan year. NCPA has been a longtime advocate of an approach that would require Sponsors to recognize retrospective pharmacy concessions – so-called "DIR Fees" – as price concessions in the "negotiated price" used to adjudicate Part D claims at the point-of-sale rather than as DIR after termination of the plan year. We continue to advocate for such an approach and fully support CMS' proposal to do just that in the 2019 Proposed Rule.

DIR Fees imposed on pharmacies participating in Medicare Part D networks by Sponsors and their pharmacy benefit managers ("PBMs") have exploded in recent years. These fees take many forms: preferred network fees, "true ups" to various effective rates, and adjustments due to performance compared to other pharmacies in Sponsors' Part D networks based on various quality measures. The treatment of these pharmacy price concessions as DIR rather than as reductions in the "negotiated price" of a drug has concerned not only NCPA, but CMS and the Medicare Payment Advisory Commission ("MedPAC") for many reasons.[3] Specifically, in certain instances, the treatment of pharmacy price concessions as DIR results in the price for certain brand and generic drugs appearing lower at preferred pharmacies when at the end of the year considering all the price concessions in DIR, the cost to beneficiaries and the Medicare Part D program as a whole is actually higher for certain drugs at preferred pharmacies than at non-preferred pharmacies.[4] In addition, by including such price concessions in DIR versus in the "negotiated price" at the point-of-sale, beneficiary cost-sharing is higher than it should be for certain drugs dispensed at certain pharmacies. More so, accounting for retrospective pharmacy price concessions as DIR rather than concessions in the "negotiated price" at the point-of-sale permits Sponsors to artificially moderate premiums at the expense of higher cost-sharing for beneficiaries.

Recently, NCPA commissioned a study of proposed federal legislation that would prohibit retroactive pharmacy payment reductions only on "clean claims" (those claims without any defect, impropriety,

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[2] *See* Attachments C and D, attached herein (NCPA surveyed its members on the impact of DIR fees on community pharmacy).

[3] *See* CMS, *Medicare Part D – Direct and Indirect Remuneration (DIR)*, Jan. 17, 2017, *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html; *see also* MedPAC, April 6-7, 2017 Meeting Agenda and Presentations including the discussion of Payment and Plan Incentives in Part D, *available at* http://www.medpac.gov/-public-meetings-/meeting-details/april-2017-public-meeting.

[4] 79 Fed. Reg. 1917, 1975 (proposed Jan. 10, 2014).

or fraud) in Medicare Part D by Wakely Consulting Group, a leading healthcare actuarial firm.[5] The study found that the elimination of retroactive pharmacy DIR Fees in Medicare Part D would save the federal government $3.4 billion over ten years in terms of reduced low income cost-sharing subsidies and lower federal re-insurance due to delay in Medicare Part D enrollees reaching the catastrophic phase of the Part D benefit. The decrease in total drug cost at point-of-sale would also lower the amount of claim dollars in the catastrophic phase of the Part D benefit because accumulated claims and amounts accumulating towards the true out-of-pocket ("TrOOP") catastrophic threshold would be lower.

Retrospective pharmacy concessions eliminate a pharmacy's ability to account for profit at the per-prescription level. A pharmacy is reimbursed at the "negotiated price" absent retrospective pharmacy concessions and such reimbursement may appear adequate and appropriate. Then, months later a Sponsor withholds large amount, suddenly making the reimbursement on the claim inadequate and perhaps lower than cost. The pharmacy is not able to forecast or model for this withholding, often not knowing the total DIR fee in advance. In most instances, cannot even allocate the aggregate withhold to the individual claims level.

Medicare Part D plans, PBMs, and their respective trade associations and agents have suggested – and likely will continue to argue – that CMS cannot mandate that retrospective pharmacy price concessions and/or a minimum percentage of manufacturer rebates be included in a drug's "negotiated price" at the point-of-sale rather than be accounted for as DIR, as to do so is contrary to the non-interference clause of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"). We vehemently disagree. CMS is not inserting itself into negotiations between Sponsors and/or their PBMs and pharmacies and pharmaceutical manufacturers by defining "negotiated price" and altering the timeframe to account for price concessions. Rather, CMS is placing parameters around the Part D benefit such as when it mandated payment of clean claims within ten days for electronic claims and fifteen days for other claims or required Sponsors or their PBMs that use a prescription drug pricing standard as the basis to pay network pharmacies update the pricing metrics on January 1st of each year and every seven days thereafter.[6] Moreover, CMS is not inserting itself into rebate negotiations between pharmaceutical manufacturers and Sponsors and/or their PBMs by providing plan design parameters for Medicare Part D plans or by regulating the minimum composition of plan formularies.[7] Sponsors and/or their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or pay structure they like just as pharmaceutical

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[5] The Wakely Consulting Group, *Impact of H.R. 1038/ S. 413 on CMS Payments Under Part D, available at* http://www.ncpa.co/pdf/wakely-report.pdf.

[6] *See* 42 C.F.R. 423.520(c) and 42 C.F.R. 423.505(b)(21), respectively.

[7] *See* 42 C.F.R. 423.104 and 42 C.F.R. 423.120(b), respectively.

manufacturers and Sponsors and/or their agents are free to negotiate any rebate amounts, terms, and conditions they choose. Moreover, CMS, as the agency delegated responsibility from Congress to oversee the Medicare Part D program, is charged with ensuring that all entities delivering the Part D benefit do so fairly, in accordance with the statutorily designed program requirements and do not manipulate or mislead beneficiaries. CMS' proposal in the 2019 Proposed Rule serves such purposes by ensuring consistent recognition of such price concessions by Sponsors such that there is a more uniform reflection of the net cost of a drug out-the-door from a pharmacy for Medicare Part D beneficiaries and CMS alike.

In addition to arguing that mandating Sponsors to include all pharmacy price concessions and a minimum percentage of manufacturers rebates in the drug's "negotiated price" at the point-of-sale violates the MMA's non-interference clause, Sponsors, PBMs and their trade associations are likely to object to inclusion of such amounts in the "negotiated price" at the point-of-sale because such amounts are not known at the time of dispensing. Such organizations might highlight that pharmacy DIR fees aimed at various quality measures such as generic dispensing rates compare such measures across the pharmacies participating in their network over the course of a year or so. In reality, there is wide variance and a complete lack of standardization across Sponsors/PBMs in the quality measures utilized, terminology, timing, and calculation. Whereas Sponsors/PBMs have a clear and defined understanding of how they are being measured, pharmacies are afforded no such opportunity. This is an area where NCPA seeks future guidance from the Agency, in order that pharmacies may have a clear and transparent shared understanding of quality goals and standards. To this end, CMS has proposed using the greatest possible concession translating into the lowest possible reimbursement as the "negotiated price."[8]

Reflecting Pharmacy Price Concessions at Point-of-Sale Would Further Uniform Reflection of Net Cost of a Drug Out-the-Door of a Pharmacy for CMS and Beneficiaries

This proposal would eliminate the need for Sponsors and their PBMs to estimate or approximate the impact of DIR Fees on "negotiated price" and ensure that all Sponsors and their PBMs are treating retrospective DIR fees in the same manner, ensuring a more level playing field. In addition, this is a process that has historical precedence in the Medicaid context under the Medicaid Drug Rebate Program. Pharmaceutical manufacturers often utilize the maximum achievable rebate when making a covered outpatient drug's Best Price determination on a quarterly basis. Best Price is then used to determine rebates due state Medicaid programs and it is "trued up" later at some periodic basis. What CMS is proposing as to the treatment of DIR fees in the "negotiated price" would achieve the same as the maximum achievable rebate methodology in the Medicaid Best Price context:

[8] 82 Fed. Reg. 56, 427 (proposed Nov. 28, 2017).

reimbursement to pharmacies based on "negotiated price" would be the lowest possible reimbursement and that could be "trued up" later in accordance with each Sponsor's or its PBM's contractual arrangement with the pharmacy.

Inevitably there will also be push back from PBMs and Sponsors related to CMS' proposal to include all pharmacy DIR fees and a minimum percentage of rebates received from Pharmaceutical manufacturers in "negotiated price" related to the limitation of current claims adjudication systems to capture and apportion these concessions on a per claim basis at the point-of-sale. It is true that PBMs will need to re-program their claims adjudication systems to appropriately capture DIR fees charged pharmacies in "negotiated price" at the point of sale. However, CMS' proposal will not be in effect until benefit year 2019 at the earliest, which should provide these entities with able time in which to implement programming changes to existing claims adjudication systems to enable capture of price concession estimates at the point of sale. The PBM industry also claimed that the mandatory maximum allowable cost ("MAC") updates that were ultimately finalized by CMS in a prior Part D rulemaking would be "operationally infeasible." In contrast to the PBM industry's claims, PBMs were more than able to upgrade claims processing systems to implement such requirements.

Reflecting Pharmacy Price Concessions at the Point-of-Sale Would Provide Needed Clarity and Transparency to the Federal Government in the Form of More Accurate Part D Bids

In addition to the cost savings that could be realized because of the proposal to include all pharmacy DIR fees at the point-of-sale, the federal government would also benefit from the standpoint of having greater clarity and consistency in the Part D bids that are submitted. Under the current system, there is a disconnect between DIR in Part D bids and the DIR reports that are submitted by plan sponsors at the end of the year. As a practical matter, the DIR projected in bids is an estimate made in early June of the preceding year, and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. In February 2017, NCPA commissioned a white paper from the Wakely Consulting Group entitled, *The Impacts of Prescription Drug Direct and Indirect Remuneration Under Medicare Part D,* that examines the various incentives that plan sponsors and PBMs may have to use post point-of-sale price concessions or DIR as well as the impact that DIR has on all the various stakeholders in the process. This report found that "plan sponsors generally have an incentive to receive price concessions in the form of DIR rather that higher point-of-sale discounts, all else being equal. This is due to the timing of when these price concessions are made or reflected in the costs, and which parties share in the costs at different stages." In addition, the report goes on to explain that the calculations in the Part D bid tool produce lower Part D bids when post point-of-sale DIR amounts are favored over discounts amounts (i.e., dollar for dollar). A lower Part D bid typically translates into increased plan sponsor profits, slightly decreased member premiums, or a

combination of the two. "While a lower bid does not come without risks to the plan sponsor, on balance our analysis shows that plan sponsors tend to generally be in a more favorable position financially if they favor post point-of-sale DIR over point-of-sale discounts."

The Wakely white paper also found that given the fact that plan Sponsors generally view DIR more financially favorable to equivalent point-of-sale discounts, "there is potential for plans to aggressively estimate DIR in bids to produce a lower bid and therefore a more competitive product. If plans are aggressive with DIR estimates, there is a greater likelihood that a risk corridor payment will be triggered, and the benefits offered may have been richer (i.e., less cost sharing) than if a more realistic DIR amount had been projected." MedPAC identified this very issue in 2015 during a presentation entitled Sharing Risk in Medicare Part D, and stated that "it is reasonable to ask if there is a financial advantage to a plan's bidding approach" or in other words using various factors to "game" the bidding process. [9]

In summary, NCPA fully supports CMS' proposal to include all pharmacy price concessions and a minimum percentage of manufacturers rebates in the drug's "negotiated price" at the point-of-sale. From an operational standpoint, NCPA would suggest that CMS utilize a phased-in approach and issue a proposed regulation to do so regarding only pharmacy price concessions as soon as possible. Given the fact that pharmacy price concessions comprise a small amount of DIR overall, CMS could move forward with implementing this change and could monitor the effects while further considering the various options outlined in the proposal that may be utilized with regard to manufacturer rebates.

Any Willing Pharmacy Standard Terms and Conditions and Better Defined Pharmacy Types

The "any willing pharmacy" provision found at Section 1860D-4(b)(10(A) of the Social Security Act is a linchpin of the Medicare Part D program and helps to ensure that beneficiaries have adequate access to pharmacy care services and prescription medications. This access is critical to ensuring that beneficiaries remain adherent to their medication regimens and can help to stave off costlier downstream medical interventions.

NCPA strongly supports the CMS' intent to further clarify the "any willing pharmacy" provision in the Medicare Part D program to establish that just because a pharmacy may have additional lines of business that may fall outside of "retail pharmacy," Part D plan sponsors may not exclude them from

[9] MedPAC, *Sharing Risk in Medicare Part D*, Mar. 5, 2015, *available at* http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0.

Part D retail networks. Many NCPA member pharmacies offer additional services to patients, for example home delivery by courier or mail, compounding, home infusion, or specialized services that focus on one or more specific disease states. Over the past year or two, NCPA pharmacy members have shared numerous accounts of situations in which Part D plan sponsors and/or PBMs have informed independent pharmacies that send filled prescriptions by mail to patients that may be living out of town for part of the year that they must cease and desist because they do not participate in a particular Part D pharmacy network as a "mail order" pharmacy. In many cases, the Part D plan/PBM has informed the pharmacy that unless they cease and desist from this activity they will effectively be "dropped" from the Part D pharmacy network. Given the fact that the pharmacy marketplace is increasingly competitive, NCPA is encouraged that the Agency is specifically emphasizing the fact that "Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network based on not fitting into the correct pharmacy type classification."

Definition of Mail-Order Pharmacy

NCPA strongly supports the CMS' decision to provide a definition of "mail order pharmacy" to provide greater clarity in the industry as well as the actual proposed definition. As mentioned in the preceding section, many independent community pharmacies provide added services for their patients, including mailing prescription refills to patients who may spend part of the year or the winter in another location. The pharmacy's willingness to do so allows the beneficiary to keep their prescription at their main "home-based" pharmacy without requiring them to shift their prescriptions to another pharmacy for part of the year. This practice also ensures continuity of care for the patient and helps to ensure that they enjoy uninterrupted access to their prescription medications and that they remain adherent. NCPA member pharmacies have increasingly been reporting situations in which Part D plan sponsors/PBMs have become aware of this practice at certain pharmacies and have informed them that the pharmacy was operating as a "mail order pharmacy." These pharmacies have been told that they must either cease and desist or otherwise risk being terminated from their retail pharmacy contract or register as a mail order pharmacy with the Part D plan sponsor/PBM network and thus pursue state licensure in all fifty states, territories, and the District of Columbia.

The lack of an actual definition of "mail order pharmacy" to date has allowed Part D plans/PBMs to use this lack of clarity to their own financial advantage. Currently the "big three" PBMs – Express Scripts, CVS Caremark and OptumRX – control between seventy-five to eighty percent of the market. Each of these companies also operates its own extremely profitable mail-order pharmacy operation. In fact, a 2017 report from Drug Channels Institute found that PBM-owned pharmacies represented

forty-six percent of the industry's revenue growth last year.[10] These same PBMs administer many of the Part D plans that were terminating independent pharmacies from Part D pharmacy networks due to their home delivery services, actions that were arguably motivated by the PBM to eliminate competition to its own mail order pharmacy. The proposed definition of "mail order pharmacy" that defines mail order pharmacy as that which provides extended-days supplies at mail order postal rates will indeed distinguish between retail pharmacies that offer some mail delivery (at retail rates) from "true" mail order pharmacies—those which have no retail presence and offer mail delivery (at mail order rates). NCPA is strongly supportive of this proposed definition and underlying policy. In addition, NCPA is supportive of the corresponding change in the definition of "retail" pharmacy.

Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions

NCPA is supportive of CMS' expectation that Part D sponsors **not** limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, **except** when necessary to meet FDA-mandated limited dispensing requirements or as required by applicable state law(s). NCPA urges CMS to codify this expectation in the final rule, and make very clear that Part D plan sponsors and their PBMs **may not** use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. NCPA members have been told by PBMs that unless their pharmacy undergoes PBM-specific credentialing, they are not able to participate in that PBM pharmacy network to dispense specialty drugs to patients of their pharmacy. These PBM-specific credentialing requirements are often required **in addition to** accreditation offerings from entities such as URAC. NCPA members should not have to pay a PBM to have that PBM apply their PBM-specific requirements on the pharmacy, often with the only goal being to reduce competition and steer patients to specific pharmacy channels in which the health plan/PBM have an ownership interest. It is also important to note that PBMs **do not** apply these PBM-specific credentialing requirements on pharmacies in any consistent manner. The PBM itself chooses which pharmacies to target and may waive these requirements at-will, depending on the pharmacy involved. To this end, NCPA greatly appreciates CMS acknowledging these concerns in the proposed rule while also recognizing the importance of upholding any willing pharmacy standard terms and conditions.

Several states have begun to address these PBM-specific credentialing requirements that are often self-serving and capricious. In 2017, both North Dakota and New Hampshire enacted laws prohibiting PBMs from requiring additional accreditation or credentialing other than the requirement of the applicable state board of pharmacy. To this end, NCPA greatly appreciates CMS continuing to recognize pharmacy practice standards established by the states provide applicable

[10] The American Prospect, *The Hidden Monopolies that Raise Drug Prices*, Mar. 28, 2017, *available at* http://prospect.org/article/hidden-monopolies-raise-drug-prices.

minimum standards for all pharmacy practice standards. Again, NCPA is supportive of CMS' expectation that Part D sponsors **not** limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies and urges CMS to codify this expectation in the final rule.

Timely Access to Standard Terms and Conditions

NCPA is strongly supportive of the proposed requirements that Part D plan sponsors have standard terms and conditions developed and ready for distribution by a date certain and that Part D plan sponsors provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request. Over the years, NCPA pharmacy members have expressed to CMS their frustration that often they have sought to participate in a Part D plans sponsor's contracted network but have been told by the plan sponsor that the standard terms and conditions are not available until the sponsor has completed all other network contracting. These actions by Plan sponsors have the effect of subverting the "any willing pharmacy" requirement of Medicare Part D. However, NCPA would suggest that the standard terms and conditions be ready for distribution on July 15th rather than August 15th. Plan sponsors have to submit their plan bids to CMS on June 1st of the preceding year and at that time must certify their pharmacy networks. In addition, the proposed September 15th deadline may be too close to the October open enrollment date. If plan sponsors wait until September 15th to present the standard terms and conditions, there is the risk that applicable pharmacy information may not be uploaded to the Medicare Plan Finder tool in a timely fashion to assist beneficiary decision making.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 Provisions

NCPA would like to voice support for CMS' conservative and uniform approach to implement the Comprehensive Addiction and Recovery Act of 2016 provisions in Medicare Part D. NCPA supports the frequently abused drug definition and urges CMS to finalize the proposal to designate opioids, except buprenorphine for medication-assisted treatment ("MAT") and injectables, as frequently abused drugs. We also strongly support that this Proposed Rule supersedes current policy, and sponsors no longer be allowed to implement the current policy for non-opioid medications. This is crucial for consistency and smooth implementation of the drug management program.

NCPA supports the exemption of hospice, cancer, and long-term care ("LTC") patients from drug management programs. We ask that in addition to these exempted individuals, CMS also exempt residents of any facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy. This could be accomplished utilizing the NCPDP Patient Residence Field. Our members who provide pharmacy services to those residing in long-term facilities provide services to assisted living facilities ("ALFs") in a very similar, if not identical, fashion. This is due to the

need ALFs have because many patients are being admitted who would most likely qualify for a LTC facility if it were not for cost-containment measures. To require a resident of an ALF to receive pharmacy services from a provider outside of normal ALF operations is not feasible and leads to disconnects in care.

We strongly support prescriber agreement to implement a pharmacy lock-in and that any notices sent from plan sponsors or PBMs be approved by the Secretary. NCPA believes it is vital that all notices sent to beneficiaries that are approved by the Secretary make very clear that any lock-in program applies only to frequently abused drugs. Our members are concerned that pharmacy lock-ins could be utilized to steer patients unknowingly to a pharmacy for **all** their drug needs, not just opioids. It is also vital that the notices do not just simply offer beneficiaries a plan sponsor/PBM created list of prescriber(s) and pharmacy(ies) from which to choose. The beneficiary must be able to write in their prescriber and pharmacy of choice and not be limited to a list provided by the plan sponsor/PBM. NCPA also supports CMS' proposal to allow the beneficiary to submit pharmacy preference at any time and asks that this be included in the final rule.

Further, NCPA agrees with CMS that the additional reference to beneficiary preference in the context of reasonable access in CARA means that a beneficiary allowable preference should prevail over a sponsor's/PBM's evaluation of geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy impact on cost-sharing and reasonable travel time.

Since preference only is to be considered by plans/PBMs when delegating prescriber/pharmacy for purposes of the Part D lock-in program, there must be protections in place for continual access. Our members have relayed to us that a very common scenario with lock-in programs is when the lock-in pharmacy is closed, the patient has no alternative to obtain their medication. In these instances, we have learned of unfortunate hospital admissions. NCPA therefore recommends that there be a back-up plan in place for a beneficiary to obtain medications when their lock-in pharmacy is closed.

The CARA Act provides that an "at-risk" patient may be "locked-in" to a pharmacy chain or group of pharmacies under common ownership and control. Also, if a PDP sponsor determines that a beneficiary's choice of pharmacy is determined to be a contributing factor in that beneficiary's "at-risk" status, the PDP sponsor may re-assign the beneficiary to another pharmacy. We feel strongly that if a PDP sponsor determines that a beneficiary's choice of pharmacy is contributing to his or her "at-risk" status and that pharmacy is part of a group of pharmacies under common ownership or control, the PDP sponsor may not simply assign that beneficiary to another location of that pharmacy chain.

We urge CMS remain vigilant in ensuring appropriate patient access. We strongly recommend that CMS require plans/PBMs report percentage of times when beneficiary preference is/is not considered and to track which pharmacy the plan/PBM utilizes to override patient preference.

Changes to the Days' Supply Required by the Part D Transition Process

NCPA is opposed to CMS' proposal to shorten the required transition days' supply in the LTC setting to the same supply currently required in the outpatient setting. Changing the current requirement for a 91 to 98-day supply of nonformulary drugs for patients transitioning from another health plan to only thirty days of medication is too drastic of a reduction. NCPA asks CMS to reconsider this proposed change and retain the current requirement or at a minimum allow for a two-month supply for LTC transitions. Pharmacists must work very carefully when faced with any need to interchange medications for nursing home residents who are stable on a drug regimen that often includes ten to twelve or more medications. There are inherent challenges to caring for these patients and often LTC pharmacists must assist in transitioning formulary alternatives in a sequence versus all at once. If all drugs that must be transitioned are to be done so in thirty days, LTC pharmacists will be unable to determine which drugs may result in adverse reactions. In addition, the entire three-month transition supply currently allowed is not dispensed all at once, so concerns with waste are most likely overstated. Again, NCPA respectfully requests that CMS reconsider this proposed change and retain the current requirement or at a minimum allow for a two-month supply for LTC transitions.

Updating Part D E-Prescribing Standards

NCPA appreciates CMS' proposal to adopt NCPDP SCRIPT Standard Version 2017071 and retirement of the current NCPDP SCRIPT Version 10.6 as the official electronic prescribing standard for transmitting prescriptions and prescription-related information for covered Part D drugs and Part D eligible individuals. NCPA equally appreciates the opportunity to provide comments on the standard and the impact of the January 1, 2019 effective date.

First, NCPA believes the sunset date of the NCPDP SCRIPT Version 10.6 should be twenty-four months from the effective date of the final rule. This would be in line with previous implementation timelines when CMS has adopted a new NCPDP SCRIPT. We believe this timeline will give the industry the adequate time to design, develop, test, certify, submit for audit, release and train end users to use the new SCRIPT version. During this twenty-four-month period, CMS should recognize NCPDP SCRIPT Version 10.6 as the officially adopted e-prescribing standard for the Medicare Part D program, but should also allow industry actors who are prepared to voluntarily implement NCPDP SCRIPT Version 2017071 earlier than this time-period.

Second, NCPA urges CMS to include the NCPDP SCRIPT 2017101 for prior authorization transactions among those it is adopting with this Proposed Rule in lieu of the current HIPAA named standard (known as "X12 278"). Electronic prior authorization is an important tool for pharmacies as it results in near-real-time adjudication decisions by Part D plan sponsors and ultimately patients receiving their prescription drugs faster. NCPA recognizes, as most of the industry does, the NCPDP SCRIPT 2017101 effectively addresses prescription drug prior authorizations better than the X12 278. CMS' adoption of the NCPDP SCRIPT 2017101 prior authorization standard is important to fast-track industry wide adoption, ultimately improving patient adherence, the reduction of physician pain points, and overall improvement of pharmacy workflows.

Prescriber Enrollment

NCPA believes the current timeline for changes to the Medicare prescriber enrollment process does not provide adequate time for industry to implement such significant changes. NCPA therefore recommends that CMS' postpone the effective date for precluded provider previsions from January 1, 2019 to January 1, 2020. Further, NCPA believes industry should be given a minimum of eighteen months after the final and complete publishing of CMS' technical guidance on such provisions to conform to the changes.

Revisions to Communication/Marketing Materials and Activities

NCPA appreciates CMS' approach to narrow the definition of "marketing" in order to focus on materials and activities that aim to influence enrollment decisions. However, the Proposed Rule attempts to make a distinction between materials that are "factually providing information about the plan or benefits versus persuasively conveying information in a manner designed to prompt the beneficiary to make a new plan decision or stay with their current plan." This approach, although well intentioned, will likely exempt from review some plan communications to beneficiaries that while they may be factual, they may also be incomplete or misleading. For example, a Part D plan recently sent a communication to a beneficiary who is also a patient of an NCPA-member pharmacy. This communication stated that a certain pharmacy chain was "preferred" and that the patient may save money by utilizing that pharmacy. The communication neglected to mention the fact that other pharmacies were also "preferred" with that plan. The end result was that the patient, relying on the communication from the plan, was left with the impression that only a certain pharmacy chain was "preferred"—although this is not the case. NCPA would recommend that CMS consider "marketing" as any communication that provides information about the plan or benefits. In addition, the difference between communications that are relaying benefit information in a "persuasive" manner versus a purely factual manner is a subjective exercise at best.

Conclusion

NCPA greatly appreciates the opportunity to share with you our comments and suggestions. If you have any questions, please contact Kala Shankle, Director of Policy and Regulatory Affairs, 703-683-1178, kala.shankle@ncpanet.org.

Sincerely,

Susan Pilch

Susan Pilch, Vice President, Policy and Regulatory Affairs
National Community Pharmacists Association

Attachments

Attachment A- The Wakely Consulting Group, *The Impacts of Prescription Drug Direct and Indirect Remuneration Under Medicare Part D*, Feb. 2017.

Attachment B- The Wakely Consulting Group, *Impact of H.R. 1038/S. 413 on CMS Payments Under Part D*, Sept. 2017, *available at* http://www.ncpa.co/pdf/wakely-report.pdf.

Attachment C- NCPA, *Report for Survey of DIR Fees Imposed on Pharmacies*, Dec. 2017.

Attachment D- NCPA, *DIR Survey Profile*, Dec. 2017.

Attachment A

National Community Pharmacists Association

The Impacts of Prescription Drug Direct and Indirect Remuneration under Medicare Part D

February 27, 2017

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Wakely

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Wakely

EXECUTIVE SUMMARY

Background

This report has been developed by Wakely Consulting Group, LLC (Wakely) for the National Community Pharmacists Association (NCPA). This report presents an analysis of the impact of direct and indirect remuneration (DIR) for prescription drugs under the Medicare Part D program on numerous different parties. We focus primarily on the financial impact to these parties involved with Part D transactions, including Part D plan sponsors, Medicare beneficiaries, the Centers for Medicare and Medicaid Services (CMS), pharmacy benefit managers (PBMs), and pharmacies and to a limited degree, drug manufacturers.

This report is intended for NCPA and may be shared with CMS. Distribution of this report to other users is limited to NCPA members, CMS, and members of Congress and their staff. We do not intend this information to benefit any third party nor create reliance by any third party on Wakely. Distribution to such parties should be made in its entirety and should be evaluated only by qualified users. Distribution to other parties should only be made with Wakely's consent.

The authors of this report are financially independent and free from conflict concerning all matters related to performing the actuarial services underlying this analysis. In addition, Wakely is organizationally and financially independent to NCPA.

Summary of Results

This report is divided into three key areas of analysis. First, we provide an in-depth description of how DIR is defined by CMS, how it fits in to the Part D program, why there are challenges related to transparency, and recent proposals and efforts to alter the treatment of DIR under Part D. Second, we provide numerical analysis of how DIR affects the multiple parties involved in all aspects of Part D transactions, and assess whether the trade-off between post-point-of-sale DIR and point-of-sale (POS) discounts is financially beneficial or harmful to each party. Third, we examine available data to assess recent trends in the amount and use of DIR in the Part D program.

Our main conclusions are summarized below.

Wakely

The Amount of DIR Has Increased in Recent Years

Both Wakely client data and national data reported by MedPAC and CMS show that the amount of DIR relative to allowed Part D costs has been increasing since 2012. In addition, the rate of increase has accelerated during years 2013 through 2015. It is unclear whether the increases are due to higher DIR dollar amounts or an increase in the classification of different forms of reimbursement as DIR. The downward trend in the national Part D bid averages every year during 2013 through 2017 also indirectly suggests increased DIR amounts.

As DIR Amounts Increase, Costs May Increase for Beneficiaries with Part D Claims

When a plan favors post-point-of-sale (POS) price concessions using post-POS DIR over POS price concessions using discounts, our analysis shows that, for Beneficiaries with Part D claims, cost sharing will be higher in all benefit phases (i.e. initial coverage limit, gap, etc.) when the Part D sponsor negotiates equivalent amounts of DIR price concessions rather than point-of-sale discounts.

Increased Use of Post-POS DIR Increases Costs to CMS in Terms of Reinsurance and Low-Income Cost-Sharing Subsidies. CMS Will Pay out Less in Low-Income Premium Subsidies.

Based on our modeling, we cannot say conclusively whether the net impact of increased post-POS DIR usage by plan sponsors has a positive or negative impact on CMS.

On one hand, we found that CMS always pays out the same or more for low-income cost-sharing (LICS) subsidies and will, on balance, pay out more for reinsurance. On the other hand, CMS will pay out less in low income premium subsidies (LIPS). The shift in price concessions from discounts to post-POS DIR can have a varying impact on federal reinsurance payouts, direct subsidies, and risk corridors. In addition, uncertainty and variation in DIR reporting (discussed further below) means that the ultimate Part D payments made by CMS may not be based on the actual paid cost as CMS intended.

Defining and Reporting DIR is Complicated, at Times Unclear, and Is Open to Interpretation

While CMS provides documents that define DIR and describe the types of DIR and how they are to be reported, we believe these definitions are not always clear. In particular, risk sharing arrangements present a challenge to plans in terms of whether to report them as DIR. The presence of related party arrangements and risk sharing is a particularly complicated scenario where there is likely to be differing interpretations as to how to characterize expenses and risk sharing cash flows.

In its communications, CMS has acknowledged that it has concern over consistency in how price concessions are reported as DIR or as adjustments to costs in the PDE files.

There is a Disconnect between DIR in Part D Bids and the DIR Reports Submitted by Plan Sponsors

As a practical matter, the DIR projected in bids is an estimate made in early June of the preceding year, and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. Given our other conclusion that most plans will view additional DIR as preferable to additional point-of-sale discounts, there is potential for plans to aggressively estimate DIR in bids in order to produce a lower bid and therefore more competitive product. If plans are aggressive with DIR estimates, there is a greater likelihood that a risk corridor payment will be triggered, and the benefits offered may have been richer (i.e. less cost sharing) than if a more realistic DIR amount had been projected.

There Is a Lack of Transparency in DIR reporting

Although reporting of DIR from PBMs to plan sponsors and plan sponsors to CMS is subject to regulation and potential audit, no such authority exists between PBMs and pharmacies, PBMs and drug manufacturers, or PBM aggregators and drug manufacturers. Current industry practice varies, but PBMs have the most control over potential DIR, and to the extent this is not frequently and readily shared with pharmacies, DIR amounts can be difficult to project.

Plan Sponsors Have Incentives to Use DIR in Part D Bids and Are Generally in a More Favorable Financial Position with Increased DIR

The calculations in the Part D bid tool produce a lower Part D bid if post-POS DIR amounts are favored over discount amounts (i.e. dollar for dollar). A lower Part D bid typically translates into increased plan sponsor profits, slightly decreased member premiums, or a combination of the two. While a lower bid does not come without risks to the plan sponsor, on balance our analysis shows that plan sponsors tend to generally be in a more favorable position financially if they favor post-POS DIR over point-of-sale discounts.

1) DEFINITION AND TYPES OF DIR

This section provides a definition of Direct and Indirect Remuneration (DIR) as used in the Part D program, a listing of the most common types of DIR used by plan sponsors and Pharmacy Benefit Managers (PBMs), how DIR is handled in Part D bids, and a brief discussion of current efforts by different interests to promote different treatment of DIR in Part D bids and reporting of DIR by plan sponsors.

Basics of the Part D Program

The Medicare Part D benefit arose from the 2003 Medicare Prescription Drug Benefit, Improvement and Modernization Act (Medicare Modernization Act, or MMA). Benefits were first made available in 2006, and included prescription drug coverage for Medicare beneficiaries who enrolled in Prescription Drug Plans (PDPs) or Medicare Advantage plans offering a Part D benefit (MA-PD). Coverage for prescription drugs was not added to the "Original Medicare" benefit.

The MMA established a "defined standard" benefit that all PDP and MA-PD plans must offer at a minimum. The federal government, through the Centers for Medicare and Medicaid Services (CMS) would provide prospective funding for a portion of the defined standard benefit and also be responsible for 80% of all claim liabilities after a beneficiary reached a designated out-of-pocket threshold.

Appendix A provides a more detailed description of how prescription drug costs under the Part D program are shared between beneficiaries, PDP/MA-PD plans, and CMS; however, this paper will focus on:

- Covered drug prices set by contracts between PDP/MA-PD plans, pharmacy benefit managers and pharmacies, and
- The use of these covered drug prices by CMS in determining its payments to plans and liabilities to beneficiaries.

DIR Definition and Its Role in the Part D Program

As noted above, CMS uses Part D sponsors' allowable costs as the basis for determining its obligations. The final rule in 42 CFR 423.308, specifies that Part D costs incurred by plan sponsors must be net of all direct or indirect remuneration (DIR) from any source that would serve to decrease the costs.

Taken from a May 31, 2016 CMS Memo[1], DIR is defined as follows:

> *Per the regulations at 42 CFR 423.308, DIR is any form of price concession, received either by the Part D sponsor or by an intermediary contracting organization (a Pharmacy Benefits Manager, or PBM, for instance) with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly.*

Although it is not entirely clear from this definition, we believe that CMS intends for DIR to represent all forms of price concessions **that cannot be determined at the point-of-sale**; therefore, throughout the remainder of this report, we will use the term DIR to mean all forms of price concessions that occur after the point-of-sale. The cost of the drug that is determined at the point-of-sale should be reported in the Prescription Drug Event (PDE) file submitted to CMS.

CMS has a vested interested in clearly defining "actual costs" of Part D sponsors (including identifying DIR), because it shares directly in Part D expenses through federal reinsurance and risk sharing (aka "risk corridors"). See Appendix A for an explanation of the Part D benefit and its associated components.

There are two main ways Part D sponsors must identify DIR. First, in the Part D bid filing, plans must submit a prospective estimate of costs to cover defined standard benefits, as well as a cost estimate to cover any benefits offered above and beyond defined standard. These costs must be net of all forms of DIR. Note that the reporting of DIR is actually labeled "Rebates" in the bid form. More detail on how DIR impacts the bid process is described in the "Impact of DIR by Party" section, below. Second, plan sponsors must submit a retrospective report of all DIR. This report must be filed by June 30 of the year following the reporting year (e.g. by June 30, 2016 for CY2015).

[1] Cheri Rice, Medicare Plan Payment Group; "Final Medicare Part D Reporting Requirements for 2015"; May 31, 2016

Types of DIR

There are many different types of DIR. In 42 CFR 423.308, the definition of "actually paid" costs notes that costs must be net of DIR, and that DIR includes the following:

- Discounts
- Charge backs
- Rebates
- Cash discounts
- Free goods contingent on a purchase agreement
- Up-front payments
- Coupons
- Goods in kind
- Free or reduced-price services
- Grants
- Other price concessions or similar benefits offered to some or all purchasers

Below we provide our interpretation of what some of these mean.

- **Discounts**. Within the context of DIR, we believe this refers to settlements related to guaranteed discounts. A settlement occurs if a PBM has guaranteed a discount off of AWP, but the actual claims are greater or less than the guarantee. For example, if a PBM guarantees that generic drugs will be 80% off AWP, but actual generic claims come in at 78% off AWP, then the additional 2% received through settlement would be classified as DIR. Note that it is possible for the DIR related to discount guarantees to be positive or negative.

  Regardless whether a guaranteed discount is in effect, the discount off of AWP that is determined at the point-of-sale is not considered DIR.

- **Chargebacks**. Payments by a wholesaler reflecting the difference between the price agreed to with a drug manufacturer and the price agreed to with a Part D sponsor.
- **Rebates**. Amounts paid by drug manufacturers after the dispensing of a drug to a Part D sponsor or intermediary such as a PBM related to specific drugs, usually brand name drugs.
- **Up-front payments**. Situations where the beneficiary has paid the full cost for a prescription and later files a claim that requires reimbursement for the portion of the cost for which the beneficiary is not liable. This would be negative DIR.
- **Coupons**. Price reductions given to beneficiaries who use certain pharmacies or drugs.
- **Goods in kind**. Non-cash items provided to beneficiaries who use certain pharmacies or drugs.

DIR Reporting, Transparency, and Consistency

When it comes to reporting and reconciling DIR, there are different interested parties, and different levels of detail that either must be reported (e.g. to CMS), or are reported as a practical matter, but are not governed by specific rules. Below, we describe how DIR is required to be reported to CMS and how DIR is reported between Part D sponsors, PBMs, and pharmacies. We provide our comments and observations regarding industry practices in reporting DIR and in submitting projections of DIR in Part D bids.

Reporting to CMS

All Part D sponsors (MA-PD and PDP plans) are required to submit a detailed report on an annual basis to CMS that shows the amount of DIR received during the calendar year. As noted above, CMS has a vested interest in determining the final price of all drugs covered under the Part D program in order to accurately calculate risk corridors and reinsurance payments. We would note that CMS only requires plans to report DIR as it relates to the defined standard benefit. Any DIR associated with enhanced benefits accrues directly to the Part D sponsor.

On an annual basis, CMS publishes a guide for reporting DIR. Below we describe the key elements in the CMS document based on the May 31, 2016 guidance.

There are two main components to the CMS DIR report[2]:

1. **Summary DIR Report**. DIR amounts are reported for each Contract and Plan Benefit Package (i.e. PBP), and must further be separated into several categories. Below is a brief list of the sub-categories in which DIR must be reported (note that the descriptions are paraphrased and are not necessarily the exact language):
    i. PBM-retained rebates. All manufacturer rebates that are retained by the PBM and not passed through to the Part D sponsor. These amounts are further separated into known amounts and estimated receivables.
    ii. Rebates received by the Part D sponsor. Differences between any guaranteed rebate amounts and actual rebates would also be included. It is important to note that this category also includes any rebates estimated at the point-of-sale. Part D sponsors must also report these estimated point-of-sale rebates in the PDE files, so although they are

[2] Cheri Rice, Medicare Plan Payment Group; "Final Medicare Part D Reporting Requirements for 2015"; May 31, 2016

submitted in the DIR report, it is necessary to remove any point-of-sale rebates reported in the PDE from the total DIR when calculating risk corridors and other reconciling items.

iii. Rebate administration fees. Excess amounts above market value for fees related to administrative services charged to manufacturers by PBMs.

iv. Price concessions for administrative services. Amounts related to administrative services provided by the PBM or drug manufacturer where the charges are below market value.

v. Legal settlements. Amounts from lawsuits or other legal action which directly or indirectly impact drugs costs incurred by the Part D sponsor.

vi. All other price concessions. All price concessions not captured in i. through v.

vii. Generic dispensing incentive payments and adjustments. Amounts paid to or received from pharmacies related to the pharmacy's performance related to the dispensing of generic prescriptions.

viii. Other pharmacy incentive payments and adjustments. Amounts paid to or received from pharmacies related to the pharmacy's performance related to any measure other than the dispensing of generic prescriptions.

ix. Risk sharing arrangement payments and adjustments. Gains or losses attributable to drug costs where the Part D sponsor receives or pays amounts related to risk-sharing arrangements with entities other than CMS. Only the provider risk arrangement impact with respect to the defined standard benefit should be reported. It is unclear where the impact with respect to benefits above and beyond defined standard should be reported, or even if they should be reported.

2. **Detailed DIR Report**. This report requires the Part D sponsor to show DIR at the National Drug Code (NDC)[3] level of detail. Like the Summary DIR report, the amounts must be shown by PBP, but only two categories of DIR are required – Rebates and All Other. The total DIR in this report must match the total from the Summary DIR Report. It is worth noting that this reporting represents an average of DIR levels across the pharmacies within the Part D sponsor's network. Any variation in DIR between different pharmacies will not be apparent.

Although CMS provides numerous details regarding the reporting of DIR, we believe there is likely varying practice across Part D sponsors in terms of what amounts are reported as DIR. In a September 29, 2014 memo from CMS[4], this inconsistency is acknowledged. Specifically, the memo states that CMS

[3] From the FDA: "Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs"

[4] Cheri Rice, Medicare Plan Payment Group; "Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions", September 29, 2014

expressed "concerns regarding the differences with which Part D sponsors report costs and price concessions to CMS".

In addition to inconsistency in reporting across different Part D sponsors, we also believe there is a high potential for inconsistency between how DIR is reported in the bids versus in the DIR reports. More specifically:

- The projected value in the bid is reported in late May or early June and is well before the actual DIR amounts become known. Although other aspects of the bid are subject to an "actual to expected" review by CMS, the DIR reporting is not one of them. Therefore, there is less compliance risk if a plan consistently reports a level of DIR in the bid that is different from that actually experienced. Despite our findings regarding the positive financial aspects of DIR for plan sponsors, there does not appear to be a strong CMS oversight or audit process to ensure that projected DIR amounts in the bid are consistent with the original filed amounts. Reporting risk sharing is challenging. If a capitation arrangement spans medical and pharmacy, plans have latitude in choosing how to allocate. Also, it is unclear whether the allocation method in the bid needs to match what is reported in the DIR report. Given the wide range of risk-sharing arrangements and related party rules in the bid instructions, it's also unclear which types of risk sharing necessitate an allocation of DIR. We also have concern that there may be a disconnect between the allocation method used by actuaries and other staff submitting bids versus different staff that determines allocations for the DIR reports.
- We have observed that the projected values in the bid are not routinely compared with previous DIR reports and actuaries typically rely heavily on the projections provided by the Part D sponsor (which are likely through the Part D sponsor's PBM).
- A June 2015 MedPac report[5] notes the following:
    - "The magnitude of DIR can be difficult for plan sponsors to predict. For example, one interviewee noted that his firm (a plan sponsor) had an especially contentious relationship with a major pharmaceutical manufacturer over rebates. At the time that bid submissions were due, the actuary believed there was only a fifty-fifty chance that the two sides could reach any agreement. In this situation, he used actuarial standards of practice—a conservative assumption about the magnitude of DIR in the sponsor's bid".
    - "...plan sponsors are required to apportion DIR evenly across spending, even if this allocation does not reflect how rebates are generated. This approach may contribute to

[5] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2015. http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0

> underestimates of spending above Part D's catastrophic threshold." More specifically, this refers to the issue that some brand drugs without therapeutic equivalents are far less likely to have rebates, yet plans must allocate DIR to these drugs.

These MedPac comments further reinforce our belief that projections of DIR in bids and allocations in DIR reporting have accuracy and consistency issues.

Reporting between the Part D Sponsor, PBMs, and Pharmacies

Of all the parties involved in the dispensing of prescription drugs under Part D (plan sponsors, beneficiaries, CMS, PBMs, and pharmacies), PBMs almost certainly have the most information. The PBMs receive pricing information from the drug manufacturers, and then contract with pharmacies and Part D sponsors.

Part D sponsors negotiate with PBMs who offer discounts off of the Average Wholesale Price (AWP) of drugs as well as expected rebates and other DIR. Often the discounts are guaranteed minimums. Separately, PBMs agree to terms with pharmacies such that the PBMs will adjudicate claims submitted by pharmacies on a script-by-script basis, with settlements related to all forms of DIR occurring at different points in time, and typically in aggregate (rather than script-by-script basis).

The reporting of reconciliations related to different forms of DIR between PBMs and pharmacies can often lack transparency. The PBM is usually in full control of the flow of information regarding the expected amount of additional liabilities or receivables with pharmacies. For example:

- If a PBM has negotiated a guaranteed discount with the Part D sponsor, only the PBM will be aware of whether that guarantee has been met, especially if the measurement period is not complete. Until the period is complete the PBM would need to estimate the pattern of drug usage for the remainder of the period in order to calculate potential liabilities or receivables from pharmacies.
- Performance-based payments (from or to the pharmacy) often depend on the PBM tracking experience relative to all members associated with a given Part D sponsor. For example, an incentive payment based on the attainment of a minimum generic dispensing rate may depend on all scripts filled by a given population and again would require a forecast of future usage if the measurement period is not complete.
- If increased discounts are given based on volume-based measures, the PBM is again likely to have better control over the underlying data. If the PBM does not regularly share the status of the measures, the pharmacy may be in the dark as to a potential increase in discounts.

Poor transparency can impact Part D sponsors. When preparing the bid, an actuary must make assumptions with incomplete DIR information. For example, if the PBM offers a guaranteed discount, the actuary must judge whether the guarantee is likely to be exceeded. The actuary's accuracy in this judgment will depend on how much information the PBM will disclose.

The lack of transparency on the part of PBMs in reporting to pharmacies can present significant challenges to pharmacies. It can be difficult to forecast financial results when there is uncertainty or a lack of reporting related to the various forms of DIR. Budgeting and contract negotiation also present challenges if DIR amounts are not well known when these activities take place. In addition, not having a full picture of final drug prices makes it more difficult to evaluate proposed contracts with PBMs and Part D sponsors, and makes it harder to assess if a given claim is consistent with the contractual terms.

Proposed Changes to the Treatment of DIR

In general, the treatment of DIR in Medicare Part D bid submissions and year-end reporting has remained consistent since the inception of the Part D program in 2006. Below we summarize some past and current efforts to alter DIR treatment.

CMS Proposal to Revise the Definition of "Negotiated Prices"

In a May 2014 proposed rule[6], CMS proposed to revise the definition of "negotiated prices" to be "...inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale". Thus, DIR arrangements such as performance-based payments or payment rates based on generic dispensing rates, market share, or other measures that could be estimated using recent experience should be applied at the point-of-sale and not be counted as DIR. The change was proposed to begin for CY2016.

Several reasons were given for this change, including:

- The original definition of DIR allowed plans to "elect which price concessions from pharmacies to report outside the PDE", which "allows price concessions to be applied disproportionately to costs that plans are liable for, and thus may shift more low-income cost-sharing subsidy and reinsurance costs to the government, as well as to manufacturers".
- Part D sponsors that shift price concessions in their favor could be at a competitive advantage versus those sponsors that do not in that a lower bid could be achieved.
- Drug prices used in the Medicare Drug Plan Finder are based on point-of-sale prices, so there is inconsistency in the pricing across plans if DIR is treated differently.

[6] Federal Register / Vol. 79, No. 100 / Friday, May 23, 2014

Ultimately, this proposed rule change was not finalized. In a November 5, 2014 memo[7], CMS indicated it reached its decision based on commenters' concerns that the revision would "effectively eliminate the regulatory exemption from negotiated price reporting for any price concessions" and on a desire to provide more time to assess Part D payment arrangements.

MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency that provides research and recommendations to the U.S. Congress regarding several aspects of the Medicare program, including Part D. Typically MedPAC produces a "Report to Congress" along with other topics of interest each year.

In recent reports, MedPAC has not offered any official recommendations related to the treatment of DIR specifically. In the June 2015 report[8], MedPAC noted that "...it would be useful to understand more about the organizational level at which plan sponsors negotiate and allocate rebates—for example, whether by individual Part D plans, by contracts, or for a company's entire book of business. The ways in which plan sponsors allocate rebate dollars across lines of business may provide large plan sponsors with flexibility as they develop bids and determine actual plan costs".

However, at the March 5, 2015 meeting of MedPAC, staff presented on the topic of "Sharing risk in Medicare Part D" and noted that the disparities between bid amounts and actual costs has very real consequences for the federal government and the Medicare program in terms of risk corridors and financial responsibility or subsidy.[9] In addition, this same presentation noted that a potential mechanism to encourage the submission of more accurate bids would be to require more plan accountability for costs that exceed the catastrophic threshold.

[7] Cheri Rice, Medicare Plan Payment Group; "Direct and Indirect Remuneration and Pharmacy Price Concessions"; November 5, 2014

[8] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2015; http://www.medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0

[9] Medicare Payment Advisory Commission, "Sharing risk in Medicare Part D," March 5, 2015; http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0

Current Proposals

In September 2016, a bill was introduced in the House, H.R. 5951, that would prohibit Part D sponsors or PBMs on behalf of Part D sponsors from retroactively reducing payments unless the claim is found to not be a "clean claim" (e.g. lack of sufficient documentation). The prohibition covers reductions only. Retroactive increases would still be allowed. This bill would certainly remove a significant portion of DIR; however, by not eliminating all forms, many of the negative aspects of DIR cited in the May 2014 CMS proposed rule[10] would still apply. However, this legislation would have a number of positive effects including ensuring that Part D beneficiaries have access to more accurate drug pricing information via Plan Finder (and can make more informed choices about their plan choice) and more clarity and accuracy for the pharmacist who will know exactly what his or her reimbursement will be at the point-of-sale.

There have also been efforts to give CMS the authority to negotiate drug prices under Part D. Currently, the "noninterference" section of the Social Security Act[11] prevents CMS from interfering with negotiations between drug manufacturers and pharmacies and Part D sponsors. For example, H.R. 3061, which was introduced July 2015, proposes to strike the non-interference section and replace it with language allowing the Secretary to negotiate prices, including discounts, rebates, and other concessions. The bill was referred to a subcommittee shortly after its introduction, with no further developments since.

There have also been efforts to give CMS authority to negotiate pricing for only certain categories of drugs such as high-cost drugs, biologics, and drugs that have no therapeutic alternative[12].

[10] Federal Register / Vol. 79, No. 100 / Friday, May 23, 2014

[11] 42 USC 1395w-111, section (i)

[12] Kaiser Family Foundation, "Searching for Savings in Medicare Drug Price Negotiations", February 9, 2016; http://kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/

2) IMPACT OF DIR BY PARTY

Introduction

In this section, we examine how different parties involved in the Part D program view DIR and are impacted by it. We consider the perspective of CMS, the beneficiary, pharmacies, PBMs, and Part D sponsors.

In addition to providing our observations on how these parties are affected, we also show how an equivalent point-of-sale discount and post-POS DIR amount impact Part D claims under different scenarios. To develop this estimated impact, we modeled how a claim would be adjudicated at different benefit phases and scenarios for an individual beneficiary. We then assessed whether the various parties to the transaction would be better or worse off with a fixed amount of discount versus the same amount of DIR. We also modeled how aggregate results trigger risk corridor payments or receivables under an assumption of the trade-off of a fixed amount of discount versus DIR.

In our analysis below we reference two scenarios according to the preference for point-of-sale discounts or post-POS DIR:

- Case 1: Point-of-sale discounts favored over DIR - in this case, the plan would receive slightly higher price concessions at point-of-sale and offsetting lower price concessions from DIR. In our modeling, we assume the plan negotiates a 20% AWP discount with a 5% rebate or DIR amount on a given drug.
- Case 2: DIR favored over point-of-sale discounts - in this case, the plan would receive slightly higher price concessions from DIR and offsetting lower price concessions at point-of-sale. Here, we assume a 15% AWP discount with a 10% rebate or DIR amount on that drug.

Federal Government (CMS)

As mentioned in previous sections, CMS has a vested interest in determining the final cost of drugs after all price concessions whether point-of-sale or post-POS. This is because CMS shares the cost of the Part D drug benefit in several ways, through:

- Federal reinsurance for claimants with catastrophic drug costs
- Low-income cost-sharing subsidies, which pay the difference between the beneficiary cost-sharing defined by the plan's benefit and the amount that an LI beneficiary pays according to the LI benefit schedule for their income category
- The risk corridor, as discussed in the Appendix
- Low-income premium subsidies, which pay for a percentage of LI beneficiaries' premiums based on their income level
- The direct subsidy, which is the portion of the Part D bid revenue subsidized by CMS

We will examine the cost impact to CMS due to the timing of drug price concessions for each of these items separately. Briefly, our findings indicate that CMS will at least some of the time pay out more for direct subsidies, risk corridor payments, and federal reinsurance when plan sponsors favor DIR over discounts.

Federal Reinsurance

Plans are required to share a portion of post-POS DIR with CMS for claims subject to federal reinsurance. In this way, federal reinsurance shares in both price concessions achieved at point-of-sale and those attained post-POS. The DIR attributable to federal reinsurance is calculated as 80% of the allowed drug costs incurred in the catastrophic phase as a percentage of total allowed costs, multiplied by the total DIR amount.

Looking at the claim adjudication examples in Exhibits A–D in the Appendix, we can draw the following conclusions:

- For claims that cross multiple benefit phases from first dollar for a defined standard or coinsurance-based benefit, federal reinsurance costs are lower under Case 1 (preferable discounts). This highlights the effect that lower price concessions at point-of-sale can have in that it can cause beneficiaries to advance through the benefit phases at a faster pace as a result of the higher drug costs incurred at point-of-sale. This may result in greater federal reinsurance costs due to beneficiaries reaching the catastrophic phase sooner and potentially incurring greater costs within the catastrophic phase once it has been reached.
- For claims incurred entirely in the catastrophic phase, federal reinsurance costs may be lower under Case 2 (DIR favored over point-of-sale discounts). However, our examples in Exhibits A–D assume a single claim, and allocate a proportionate share of DIR to reinsurance from that single claim. This differs from the reality of how DIR is allocated to reinsurance in that the reduction for DIR attributable to federal reinsurance is done in aggregate at the individual plan-level (i.e. Contract and PBP), rather than at the claim level. Therefore, it is possible that Case 2 may not produce lower costs depending on the amount of DIR actually allocated to federal reinsurance, which would be dependent on the individual plan's annual claim experience in aggregate.

Low-Income Cost-Sharing Subsidy (LICS)

Within Part D, there are defined benefit schedules for LI beneficiaries which run parallel to the benefit plan that the beneficiary is enrolled in. There are four distinct LI benefit schedules, and the beneficiary's income level defines which schedule or category applies to the beneficiary. LICS is then calculated as the difference between the beneficiary's cost-sharing defined by the benefit plan that they enrolled in and the amount the beneficiary actually pays according to their particular LI benefit schedule. Therefore, the impact of the timing of drug price concessions on LICS is similar to the impact on beneficiaries' cost-sharing as discussed later in the report:

- LICS is equal or greater in all scenarios under Case 2 (preferable DIR) versus Case 1 (preferable discounts).

- LICS is lower under Case 1 in the following instances:
    - All phases of the defined standard benefit – therefore any benefit design using a deductible, a coinsurance-based benefit, and a defined standard catastrophic benefit
    - Claims in either the initial coverage phase or coverage gap when there is a co-pay benefit but the allowed cost falls below the co-pay
- When the allowed cost of a drug claim is higher than the copay amount, then LICS is unaffected by the type of price concession since the copayment is the same in either case.

We considered the most extreme case of LICS in our examples in Exhibits C–D in the Appendix: institutional LI beneficiaries. For this particular LI category, the beneficiary actually pays $0 for all drugs in all benefit phases, resulting in the highest possible LICS amount equal to the beneficiary's cost-sharing responsibility as defined by the plan's benefits.

We draw the same conclusions from our examples as those we listed in the "Beneficiary" section later in the report. However, we still modeled this case separately since LI members have a defined standard gap benefit that differs from non-LI members. Therefore, dollar amounts in Exhibits C and D may differ slightly from those in A and B.

Risk Corridor

In Exhibit F in the Appendix, we examine the impact on plan costs with respect to the risk corridor. Exhibit F-1 considers scenarios where actual costs fall within +/- 5% to 10% of expected costs, whereas Exhibit F-2 considers scenarios where actual costs fall within +/- 10% or more of expected costs. Within both exhibits, we look at a scenario with favorable experience where actual costs are lower than expected costs as well as a scenario with unfavorable experience where actual costs exceed expected costs.

When considering the impact on CMS's costs, we focus solely on the risk corridor transfer amounts. Exhibit F shows that in these examples, Case 1 produces a more favorable risk corridor transfer amount for CMS than Case 2 when the plan's actual experience is worse than expected, and vice versa. However, results may vary depending on the amount of price concessions being shifted from POS discounts to post-POS DIR, and resulting changes in the federal reinsurance and plan benefit ratios (i.e. paid-to-allowed ratios).

In recent years, CMS has collected more in risk corridor transfers than it has paid in aggregate for all MA-PD and PDP plans. Therefore, if this relationship holds, it would be in CMS's best interest, from a risk corridor perspective, if Part D plan sponsors shift price concessions away from POS discounts and into post-POS DIR.

Low-Income Premium Subsidy (LIPS)

CMS subsidizes beneficiary premiums for LI individuals to varying degrees depending on the individual's income level. Therefore, any price concession arrangement that serves to reduce beneficiary premiums would also reduce CMS's costs for LIPS amounts. Greater reductions in plan costs due to DIR can result in lower beneficiary premiums, and as a result lower CMS payments for LIPS amounts.

Direct Subsidy

CMS pays Part D plan sponsors a "direct subsidy" for each beneficiary, which is equal to the beneficiary's risk score multiplied by the plan's Part D bid amount, less the plan's basic premium amount. An illustration of the development of the direct subsidy is shown in Table 1 in the Appendix.

Exhibit G in the Appendix shows a pricing illustration under the same two price concession scenarios discussed in other sections above: Case 1 (preferable discounts) and Case 2 (preferable DIR). We then examine the impact on the CMS direct subsidy for different members based on the estimated Part D bid amount from each scenario. In our examples, Case 2 results in a lower Part D bid amount than Case 1 as shown in Table G-1 in the exhibit. In Table G-2 we see that the CMS direct subsidy is lower when the Part D bid is higher (as it is in Case 1) for risk scores less than 1.0. Conversely, the CMS direct subsidy is higher when the Part D bid is lower (as it is in Case 2) for risk scores greater than 1.0.

Therefore, the impact on CMS's costs associated with the direct subsidy due to the timing of price concessions (POS discounts vs. post-POS DIR) will vary based on members' risk scores. In theory, this should have a minimal impact on the overall direct subsidy amount for all Part D members given that risk scores are expected to average a 1.0 risk score. However, this effect could cause an overall increase or decrease in the direct subsidy depending on the distribution of risk scores for members within plans favoring POS discounts vs. post-POS DIR.

Beneficiaries

From the beneficiary perspective, a plan that favors DIR over point-of-sale price concessions presents a trade-off between a slight reduction in premium versus the same or higher cost-sharing under most conditions for those who have Part D claims. Price concessions due to DIR may enable plans to pass that savings onto the members in the form of slightly lower premiums or richer enhanced benefits (medical or drug); however, beneficiaries with Part D claims may also find themselves paying more out-of-pocket because forgone discounts are no longer shared. This is discussed further in the "Part D Plan Sponsors" section below.

For example, consider if a plan had the option of receiving price concessions in the form of Case 1 (20% AWP discount and 5% rebate or DIR amount on a drug), or Case 2 (15% AWP discount with a 10% rebate or DIR amount on that drug). Both options would result in the same price concession; however, the first

option (Case 1) may share more of the savings with the claimant taking that drug, whereas the second option (Case 2) may share more of the savings with all members in the form of lower premiums.

In looking at the claim adjudication examples in Exhibits A and B in the Appendix, we can draw the following conclusions:

- Beneficiaries pay an equal or greater amount out-of-pocket under all scenarios under Case 2 (preferable DIR) versus Case 1 (preferable discounts), ignoring member premiums.
- Beneficiary out-of-pocket costs are lower under Case 1 in the following instances:
    - All phases of the defined standard benefit – therefore any benefit design using a deductible, a coinsurance-based benefit, and a defined standard catastrophic benefit
    - Claims in either the initial coverage phase or coverage gap when there is a co-pay benefit but the allowed cost falls below the co-pay
- When the allowed cost of a drug claim is higher than the copay amount, then beneficiary out-of-pocket costs are unaffected by the type of price concession since the copayment is the same in either case.

Higher negotiated costs at point-of-sale with greater price concessions post-POS (i.e. Case 2) may also result in claimants potentially not filling their prescription if the beneficiary's cost-sharing is too expensive for them to afford. If this were to happen, it could also have a negative effect on the plan sponsor in the form of lower drug adherence (a Medicare quality measure), or greater member attrition.

Some plans may even delay adding cheaper generic alternatives to some brand drugs to the formulary in some instances due to the high rebates they can receive from the drug manufacturer, despite that this can increase particular claimants' costs even if it does also serve to lower premiums slightly for all beneficiaries.

Pharmacies

Pharmacies are at a distinct disadvantage when price concessions are taken or collected from pharmacies after the point-of-sale. The main reason for this is a distinct lack of transparency in the detail provided to pharmacies both at contract initiation and when calculations supporting DIR amounts are provided. Even though DIR fees are usually determined on a claim by claim basis, in practice they are assessed or charged to the pharmacy as a lump sum without claim-specific detail. In addition, DIR fees are assessed post-adjudication, or retroactively, which creates operational and cash flow challenges for the pharmacies.

This situation is further complicated by the fact that pharmacies are reimbursed for virtually all generic drugs (approximately 88% of all drugs dispensed) via "Maximum Allowable Cost" (MAC) lists—that are created, maintained and changed at the sole discretion of PBMs. The pharmacist does not "find out" what they will be reimbursed for any generic drug until such time as the claim is adjudicated or submitted to the PBM for payment just prior to that drug being dispensed to a patient. From a practical

standpoint, a pharmacy believes they are being reimbursed a certain amount based on the remittance they receive at the time the claim is adjudicated. However, once DIR fees are assessed months later, the ultimate reimbursement on that claim or any claim may be significantly lower. Typically, most PBMs do not provide any claim-level detail to pharmacies that would provide them with a clear picture as to how much money was extracted from each individual claim. In addition, without this level of detail, it is virtually impossible for the pharmacy to determine exactly what their reimbursement was for each claim or conversely how much money they lost. All of these factors make it extremely challenging for pharmacies both from a cash flow and business planning perspective.

It is also important to point out that pharmacies are also at a distinct disadvantage in terms of negotiating power with PBMs—particularly independent community pharmacies. The PBM marketplace is extremely concentrated and nearly three-quarters of all prescription claims were processed by just three companies[13]. Large pharmacy chains can certainly use their market power to attempt to push back on PBMs on pricing and payment practices; however, independent community pharmacies—even those who are represented by Pharmacy Services Administrative Organizations (PSAOs)—typically have very little negotiating power and often must agree to the offered terms or lose potential prescription business. Also, as detailed above, PBMs have virtually unilateral control over the pricing for 88% of all drugs dispensed and therefore have the ability to manipulate the interplay between the contractual pricing terms, the MAC list amounts and the DIR calculations affected by these prices.

Pharmacy Benefit Managers

Based on our analysis of the impact of favoring DIR over point-of-sale discounts on other parties, it is apparent that pharmacy benefit managers (PBMs) will have several incentives to favor DIR.

First, it is common in the terms of PBM contracts with Part D plan sponsors for the PBM to retain a portion of rebates (a form of DIR) in lieu of higher PBM fees.

Second, as discussed below, plan sponsors have several reasons to favor DIR over point-of-sale discounts. The PBM will certainly seek to attract plan sponsor business partners, and has the data to effectively determine a DIR structure equivalent to a given point-of-sale discount.

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[13] http://www.coapharmacy.com/hearing-the-state-of-competition-in-the-pharmacy-benefit-manager-and-pharmacy-marketplaces/

Third, PBMs retain control over claim data and MAC pricing. To the extent that DIR arrangements are based on performance where MAC pricing is a factor, the PBM has the ability to continuously modify pricing to produce results that are financially favorable for the PBM.

An indirect consequence of increased DIR is that drug pricing is less transparent for both the Part D sponsor plans and pharmacies. This gives PBMs significant leverage in negotiations.

Part D Plan Sponsors

Part D plan sponsors generally have an incentive to receive price concessions in the form of DIR rather than higher AWP discounts, all else being equal. This is due to the timing of when these price concessions are made or reflected in the costs, and which parties share in the costs at different stages. To illustrate this, we must consider how price concessions through discounts and DIR are treated from a claims perspective as well as in the CMS Part D Bid Pricing Tool (BPT).

As shown in Table 2.1 below, drug costs begin with a gross amount, typically the AWP, before any negotiated point-of-sale discounts. After applying reductions due to point-of-sale (POS) discounts, we arrive at the allowed amount. This allowed amount is used as the starting cost when the claim is adjudicated through the plan's benefit, and therefore it is used as the basis to calculate what other payers' (i.e. beneficiaries, CMS, and drug manufacturers where applicable) amounts will be at POS for the claim. Then, once post-POS DIR is available, plan costs and federal reinsurance are further reduced by a proportionate amount of any post-POS DIR. As a result, price concessions due to discounts, which are known at POS, are shared by the plan, beneficiary, drug manufacturers, and CMS; whereas, price concessions due to post-POS DIR are only shared by the plan and CMS, and can therefore be more beneficial to the plan in many scenarios, all else being equal. Note that the last row in Table 2.1 shows that drug costs net of discounts and DIR are equal in both cases. The difference in the final plan cost is attributable to the amount of price concessions available at POS vs. post-POS.

Table 2.1 – Illustration of Payer's Costs at Point-of-Sale and After Post-POS DIR Adjustments

		Case 1: Preferable Discounts	Case 2: Preferable DIR
A	Drug Cost Gross of Discounts	$300	$300
	Point-of-Sale		
B	Allowed Cost (Net of Discounts)	$240	$255
C	Beneficiary Cost-Sharing	$69	$71
D	Manufacturer Gap Discount	$61	$63
E	Federal Reinsurance Gross of DIR	$88	$91
F = B – (C+D+E)	**Plan Cost Before Reductions Due to DIR**	**$21**	**$30**
	After Point-of-Sale		
G	Total DIR	$15	$30
H = G * E / B	DIR Allocated to Federal Reinsurance	$6	$11
I = G – H	Plan-Retained DIR	$9	$19
J = E – H	Federal Reinsurance Net of DIR	$83	$80
K = F – I	**Plan Cost After Reductions Due to DIR**	**$12**	**$10**
L = B – G	Drug Costs Net of Discounts and DIR	$225	$225

In the Part D BPT, it is the plan cost after reductions due to DIR (i.e. item K from the above table) that would then be grossed up for non-benefit (administrative) expenses and profit margin to calculate the plan's Part D bid amount and beneficiary premiums. Therefore, greater reductions in plan costs due to DIR can result in lower Part D bid amounts and beneficiary premiums. This may give the plan a competitive advantage if they are able to offer beneficiaries either a comparable benefit plan at a lower premium, or alternatively a richer enhanced benefit at a premium that is comparable to their competitors.

Several other examples like those shown in Table 2.1 above are provided in Exhibits A – D in the Appendix. There, we examine the cost impact (after all price concessions) on each party or payer for a single claim under various scenarios: within each benefit phase, for a defined standard benefit with deductibles and coinsurance vs. an enhanced co-pay benefit structure, and separately for a non-low-income (NLI) individual vs. an institutional low-income (LI) individual. In each scenario, we conclude whether each party's costs would be lower under Case 1 (discounts favored) and Case 2 (DIR favored).

Our conclusions from the analyses and examples shown in Exhibits A through D are as follows:

- Part D plan sponsor costs are lower under Case 2 in the following instances:
  - Claims in the deductible phase
  - Claims in either the initial coverage phase or coverage gap when there is a coinsurance

benefit or if there is a co-pay benefit but the allowed cost falls below the co-pay

- Part D plan sponsor costs are lower under Case 1 in the following instances:
  - Claims in the catastrophic phase
  - Claims crossing multiple benefit phases, with a fair amount of costs falling in the catastrophic phase
- Part D plan sponsor costs are unaffected by the type of price concession for claims in the initial coverage phase or coverage gap if there is a co-pay benefit and the allowed cost exceeds the co-pay

We would expect the savings due to a preferable POS discount arrangement to generally be overshadowed by the savings generated by a preferable post-POS DIR arrangement for most plans, resulting in a preference on the Part D plans' part to seek out arrangements that shift price concessions from POS discounts to post-POS DIR.

In Exhibit F in the Appendix, we also examined the impact on plan costs with respect to the risk corridor. Exhibit F-1 considers scenarios where actual costs fall within +/- 5% to 10% of expected costs, whereas Exhibit F-2 considers scenarios where actual costs fall within +/- 10% or more of expected costs. Within both exhibits, we look at a scenario with favorable experience where actual costs are lower than expected costs as well as a scenario with unfavorable experience where actual costs exceed expected costs.

In each of the scenarios shown in Exhibit F, it is more favorable to the Part D Plan Sponsor to have a preferable DIR arrangement with slightly higher price concessions from DIR and offsetting lower price concessions from discounts when considering the plan's final costs after all price concessions and risk corridor. Despite that the plan's risk corridor payable is higher under Case 2 for scenarios where the plan has favorable experience, the plan's overall costs are still lower under Case 2 due to the added savings from DIR.

Drug Manufacturers

Beginning in 2011, the Affordable Care Act required drug manufacturers to pay a "coverage gap discount" (CGDP) amount for brand drugs incurred by non-LI beneficiaries in the coverage gap in an effort to eventually eliminate the coverage gap by 2020 from a beneficiary cost-sharing perspective. The CGDP amount is based on the point-of-sale allowed cost of the drug under the defined standard gap benefit, and does not receive any proportionate share of post-POS price concessions from DIR. Under an enhanced gap benefit, the CGDP amount is calculated as a percentage of the beneficiary's cost-sharing rather than the allowed cost.

In looking at the claim adjudication examples in Exhibits A–B in the Appendix, we can draw the following conclusions:

- In all scenarios, manufacturers will pay an equal or greater amount of CGDP under Case 2 (DIR favored) versus Case 1 (point-of-sale discounts favored).
- CGDP costs are lower under Case 1 when:
    - A non-LI beneficiary in the coverage gap phase of a *defined standard* design has a brand drug claim.
    - A non-LI beneficiary in the coverage gap phase of an *enhanced gap benefit design using co-payments* has a brand claim where the allowed cost falls below the co-pay
- CGDP costs are unaffected by the type of price concession (Case 1 or Case 2) when:
    - A non-LI beneficiary in the coverage gap phase of an *enhanced gap benefit design using copayments* has a brand claim where the allowed cost exceeds the co-pay.
    - A claim is for a generic drug
    - The beneficiary has LI status

Another important consideration is that when point-of-sale drug costs are higher (Case 2: DIR favored), beneficiaries will reach the coverage gap faster (all other factors being equal). As more beneficiaries reach the coverage gap, more claims will be in the gap and CGDP costs will be higher.

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3) TRENDS IN AMOUNT AND TYPES OF DIR

Background

In general, the usage of DIR under Part D by plan sponsors and PBMs has increased in terms of both dollar amounts and types of reimbursement classified as DIR over the last few years. We believe this is primarily due to the strong incentives created by the bid process for Part D sponsors and PBMs to use DIR.

Trends in DIR Reported in Part D bids

Both national data and Wakely client data show that there has been an increase in the per member per month (PMPM) amount of DIR reported in Part D bids over the last few years. A similar increase can also be seen when DIR is expressed as a percentage of total Part D prescription drug spend.

These conclusions are based on an analysis of Wakely clients who have filed Part D bids for contract years 2014 through 2017 and information provided in the March 2016 MedPAC report "Medicare Payment Policy: Report to Congress".

<u>Wakely Client Averages</u>

The analysis of Wakely clients shows a steady increase in the actual (as opposed to projected) DIR PMPM and DIR as a percentage of allowed in 2012 through 2015. Table 3.1 shows our results. Please note that the term "Rebates" is used in the bid filings, but we use the term DIR below.

Table 3.1
DIR Reported in Medicare Part D Bids
Wakely Client Average

Experience Year	Bid Filing Year	DIR PMPM	Annual Trend	DIR as % of Allowed	Annual Trend
2012	2014	$6.48		4.5%	
2013	2015	$7.20	11.1%	5.0%	11.2%
2014	2016	$9.02	25.3%	5.4%	8.3%
2015	2017	$16.09	78.3%	8.3%	54.0%

The average DIR PMPM in Table 3.1 is increasing each year, and increased very significantly in 2015, indicating that either amounts or types of DIR or both are being used by Part D sponsors and affiliated PBMs. The PMPM trend is also outpacing the trend in overall Part D drug spend, as can be seen by the increasing DIR as a percentage of allowed by year in Table 3.1.

In addition to these actual DIR amounts, the projected DIR in Part D bid filings has also been increasing. The projected DIR represents the Part D sponsor's estimate of all types of DIR it expects the PBM to collect (or pay) in the contract year. The average projected DIR for Wakely clients was consistently higher than the base period DIR, both as a PMPM and as a percentage of allowed costs. Table 3.2 shows the Wakely client averages for projected DIR by contract year.

Table 3.2
DIR Projected in Medicare Part D Bids
Wakely Client Average

Bid Filing Year	DIR PMPM	Annual Trend	DIR as % of Allowed	Annual Trend
2014	$9.42		6.5%	
2015	$10.25	8.7%	5.7%	-13.0%
2016	$11.54	12.7%	5.9%	4.2%
2017	$22.11	91.5%	9.8%	64.7%

Table 3.2 shows that projected DIR is increasing by year, and that plans are projecting increases in DIR amounts from the base period to the contract period. For example, for CY2014 bid filings, the average base period DIR PMPM was $6.48 (Table 3.1) for 2012, and the projected value for 2014 was $9.41 (Table 3.2), or 45% higher.

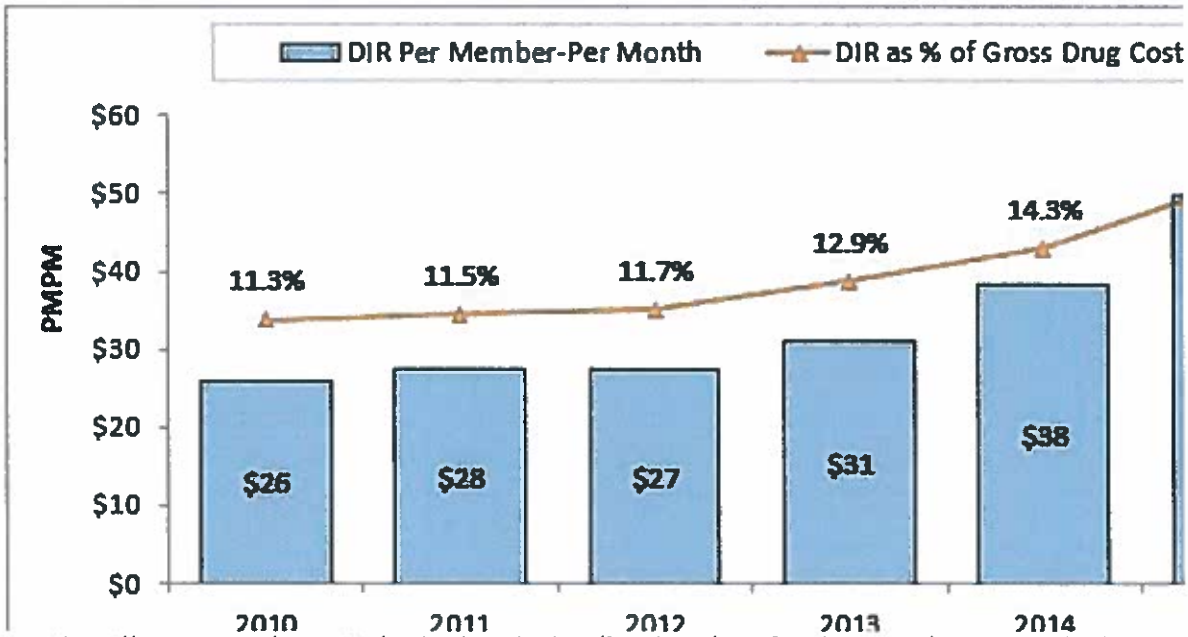
The Wakely client averages are based on all individual Part D bid filings for plans with experience that was at least 90% credible, based on the CMS formula (credibility % = SQRT(member months ÷ 18,000)). We further limited the bids used by excluding all special needs plans (i.e. dual eligible SNPs and chronic condition SNPs).

National Averages

CMS Fact Sheet

Recently, CMS released a Fact Sheet demonstrating significant growth in DIR in 2010 through 2015. Nationally, the average DIR PMPM and DIR as a percentage of gross drug costs has gone up since 2012, as shown in CMS's Figure 1:

Figure 1 – DIR by Payment Year



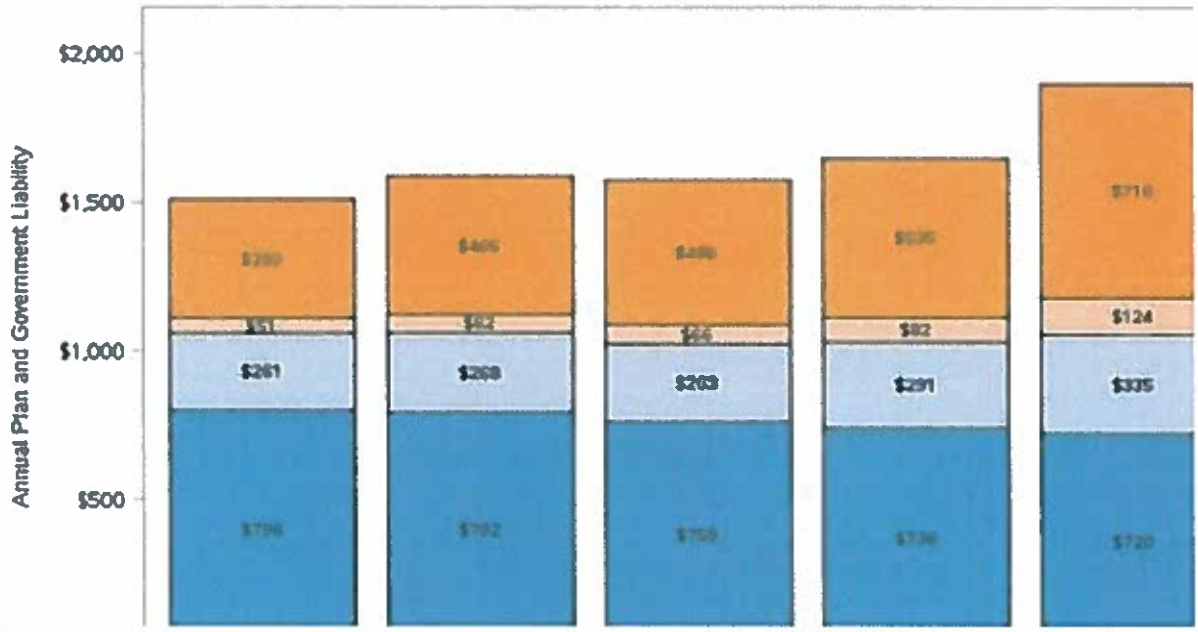
Source: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

Not only have the costs been increasing, but the growth has been accelerating.

The impact of these increasing DIR amounts that CMS describes is similar to our analysis in the "Impact of DIR by Party" section earlier in this report. CMS notes that DIR does not reduce the cost of drugs at the point-of-sale; therefore potentially increasing beneficiary out-of-pocket costs. On the other hand, plan sponsors are seeing reduced plan liabilities as a result of increased DIR. In particular, high cost specialty drugs often coupled with high rebates have pushed more beneficiaries into the catastrophic phase of the Part D benefit, where plans are only responsible for approximately 15% of costs. The result is that the high-price, high-DIR trend disproportionately reduces plan liability.

Figure 3 from the CMS Fact Sheet shows a downward trend in plan liability as DIR has increased. It also shows that federal reinsurance spending has continued to increase even though DIR allocated to federal reinsurance has also increased.

Figure 3 – Final Annual Medicare Reinsurance and Plan Liability per Beneficiary[2]



Source: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

Finally, the Fact Sheet also acknowledges that low-income cost-sharing payments are higher with the increased use of DIR since the benefits of reduced drug costs do not occur at the point-of-sale and thus are not shared with CMS in these instances.

MedPac Reports and the National Average Part D Bid

There are some other national measures that also point to increased amounts and usage of DIR in Part D.

First, the March 2016 MedPAC report[14] reported the DIR as a percentage of total allowed Part D costs have increased significantly from 2007 through 2015. Table 3.3 shows these statistics.

[14] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, March 2016; http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0

Table 3.3 DIR Projected in Medicare Part D Bids Nationwide Average		
Experience Year	**DIR[1] as % of Allowed**	**Annualized Increase**
2007	9.6%	
2013	12.9%	5.0%
2014	14.4%	11.6%
2015	16.6%	15.3%
[1] Labeled "Rebates" in MedPAC report		

Similar to the CMS Fact Sheet and Wakely client averages, the MedPac reported data shows an acceleration in the amount of DIR used in the Part D program.

Second, though not explicit, increased DIR may be a cause of the counter-intuitive decreasing trend in the National Average Bid Amount (NABA) for Part D bid in recent years. The NABA represents a member-weighted average of all MA-PD and PDP plans' estimate to cover the defined standard benefit in a given year. Table 3.4 shows the NABA since 2011.

Table 3.4 History of National Average Bid Amount		
Year	**NABA**	**Trend**
2011	$84.50	
2012	$87.05	3.0%
2013	$79.64	-8.5%
2014	$75.88	-4.7%
2015	$70.18	-7.5%
2016	$64.66	-7.9%
2017	$61.08	-5.5%

Table 3.4 shows a clear pattern of the NABA decreasing each year since 2012. There are many factors that influence the NABA such as the parameters underlying the defined standard benefit, trends in drug prices, the mix of brand versus generic drug usage, contracts negotiated between carriers and PBMs, the changing membership by carrier which drives the weighted average, and other factors. Given all of these potential drivers, it is more difficult to confidently say that increased DIR is a cause; however, there are at least some reasons to think it is a reasonably possibility:

- The defined standard benefit parameters have generally kept pace with drug cost inflation, and in recent years have actually contributed to positive expected trend in the defined standard benefit due to the increased plan liability in the gap imposed by the Affordable Care Act.
- In every year since 2012, UnitedHealth Group, Inc., Humana Inc., and CVS Health Corporation have captured about 50% of the total Part D marketplace, so a significant portion of the NABA is driven by the same carriers each year. Given that it is unlikely these carriers are able to negotiate increasing discounts each year, it also seems very plausible that increased use of DIR is a major contributing factor – both in terms of the amount and in terms of additional forms or drug reimbursement being classified as DIR.
- Total drug cost trends have been non-negative over this time period. The annual Express Scripts Drug Trend Report showed flat or positive trend over 2013 through 2015. Table 3.5 shows these estimated trends.

Table 3.5

Express Scripts Medicare Drug Trends[15]

Year	Traditional	Specialty	Total
2015	4.80%	27.90%	10.90%
2014	6.40%	45.90%	13.80%
2013	0.00%	14.70%	2.60%

Although the very high specialty drug trends have a diluted impact on the defined standard benefit (i.e. because plan liability is very much reduced above the initial coverage limit and in the catastrophic benefit phase), even the traditional, non-specialty drug trends have been positive.

[15] Express Scripts 2015 Drug Trend Report, March 2016; The 2014 Drug Trend Report, Express Scripts, March 2015; The 2013 Drug Trend Report, Express Scripts, April 2014

4) CONCLUSIONS

Trying to ascertain the impact of DIR on the Part D and its various invested parties is a broad and complicated task. This report has analyzed several aspects of this question, and we believe the following conclusions can be made.

- The amount of DIR reported in Medicare Part D bids has steadily increased since the inception of the Part D program. Based on Wakely client data, there appears to be an acceleration in the amount of DIR in 2015 and projected DIR in 2017 bids. Recent downward trends in the national average Part D bid also support the idea that DIR is increasing.
- The trade-off between equivalent amounts of DIR versus point-of-sale discounts is financially advantageous to Part D sponsors except in limited situations. The mechanics of the bid form produce a lower bid if DIR is favored over discounts, and Part D sponsors will most typically desire a lower bid in order to offer a more competitive product and gain market share. Favoring DIR over discounts also means that Part D sponsors will share price concessions only with CMS rather than CMS, drug manufacturers, and beneficiaries (claimants). Also, sponsors will fare better using DIR under all scenarios where a risk corridor payment is made, regardless whether the sponsor pays CMS or CMS pays the sponsor.
- From a cost-sharing perspective, beneficiaries are worse off if the Part D sponsor favors DIR over discounts. This is not the entire story; however, as use of DIR will ultimately result in lower premiums or enhanced benefits for beneficiaries. Given these opposite impacts, the net effect is essentially that use of DIR has some positive impact on all members of the plan while having a negative impact on individuals with Part D claims.
- CMS will pay out the same or more in low-income cost-sharing if sponsors favor DIR. On the other hand, CMS is likely better off on balance from a low-income premium subsidy and risk corridor perspective if plan sponsors favor DIR. CMS is not consistently better or worse off in terms of direct subsidy or federal reinsurance payments if Part D sponsors favor DIR.
- The primary difficulty for pharmacies is a lack of transparency in claims, which makes it difficult to estimate cash flows, budget for the future, and evaluate proposed contracts from PBMs. The increased use of DIR compounds these issues even further.
- There appears to be inconsistent practices of what reimbursement is reported as DIR versus inclusion in the PDE reports. The broad range of types of DIR, uncertainty in their definitions, and allocation decisions that have a wide range of interpretation are contributing factors to this inconsistency.
- We believe there is a disconnect between the projected DIR submitted in Part D bids and the DIR submitted to CMS in the Summary and Detailed DIR reports. Given plans' confusion as to what to report as DIR, and the lack of audit oversight by CMS, it is possible that the assumptions used in bids may not reconcile well with the values in the DIR reports. This disconnect presents a risk that Part D sponsors will be more or less aggressive in submitting bids as compared with actual DIR.

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Appendix A

Part D Defined Standard Benefit and Claim Obligations of CMS and Beneficiaries

The Medicare Part D benefit arose from the 2003 Medicare Prescription Drug Benefit, Improvement and Modernization Act (Medicare Modernization Act, or MMA). Benefits were first made available in 2006, and included prescription drug coverage for Medicare beneficiaries who enrolled in Prescription Drug Plans (PDPs) or Medicare Advantage plans offering a Part D benefit (MA-PD). Coverage for prescription drugs was not added to the "Original Medicare" benefit.

Defined Standard Benefit

The MMA established a "defined standard" benefit that all PDP and MA-PD plans must offer at a minimum. The federal government, through the Centers for Medicare and Medicaid Services (CMS) would provide prospective funding for a portion of the defined standard benefit and also be responsible for 80% of all claim liabilities after a beneficiary reached a designated out-of-pocket maximum.

The defined standard benefit has followed the same basic structure since 2006, with some adjustments imposed by the Affordable Care Act, and is defined as follows:

- The beneficiary is responsible for all initial expenses up to a deductible (for 2017, it is $400).
- The beneficiary and PDP/MA-PD plan share all expenses on a 25%/75% basis for all covered Part D drug expenses between the deductible and an initial coverage limit ("ICL", which was $3,700 for 2017).
- Expenses above the ICL are shared between the beneficiary, the PDP/MA-PD plan, and drug manufacturers until the beneficiary reaches a catastrophic True Out-of-Pocket (TrOOP) limit. The beneficiary's cost-sharing depends on whether the drug is generic or brand and whether the beneficiary is low-income (LI) or non-LI. For generic drugs, a non-LI beneficiary is responsible for a portion of total expenses on a schedule that grades down to ultimately be 25% in 2020. For 2017, the percentage is 51%. For brand drugs incurred by a non-LI beneficiary, drug manufacturers must pay 50% of the negotiated drug cost, with the beneficiary and PDP/MA-PD plan splitting the remaining 50% on a schedule that again ultimately has the beneficiary paying 25% by 2020. For 2017, the brand drug coinsurance split between beneficiary and plan is 40% and 10%, respectively. For LI members, the member is responsible for 100% of the cost in the coverage gap, which is heavily subsidized by low-income cost-sharing subsidies.

Exhibit 1.1 below shows a graphic of which party is responsible at different levels of total Part D claim spend.

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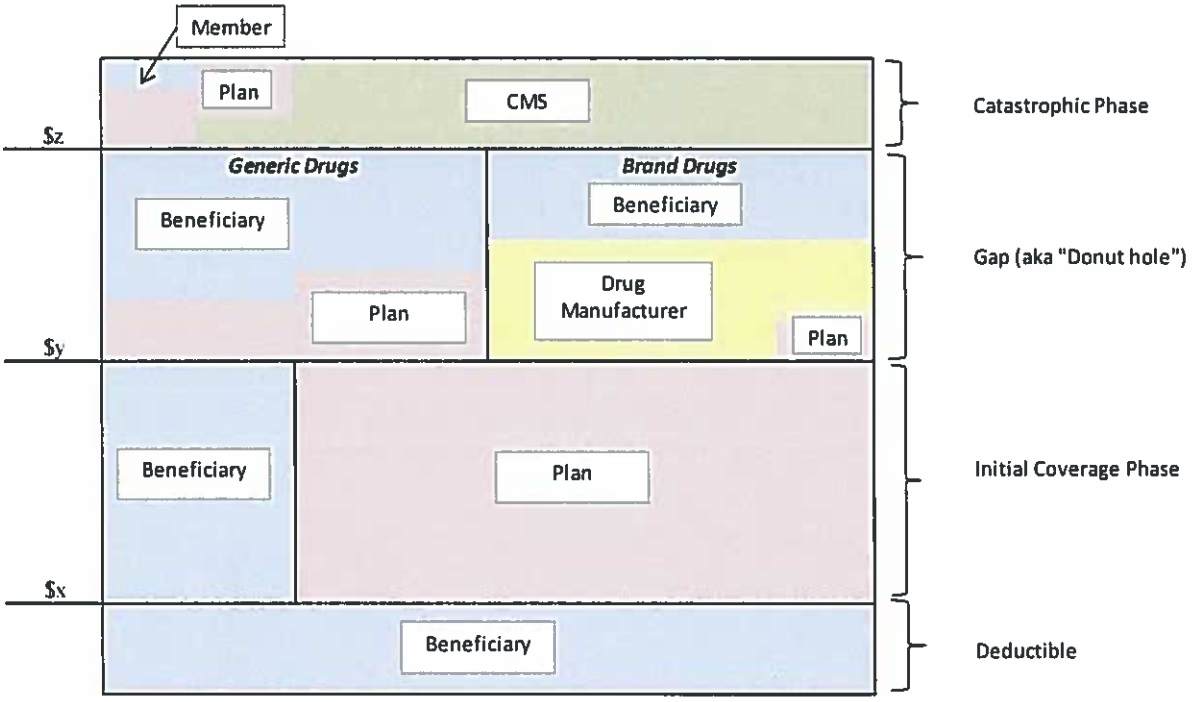
Exhibit 1.1
CMS Defined Standard Part D Drug Benefit
Non Low-Income Member



Direct Subsidy

The prospective payment amount paid by CMS is called the "direct subsidy" and is determined as: Plan-specific 1.00 "Basic Bid" x Part D Risk Score – Basic Premium, where:

- The 1.00 Basic Bid is the PDP or MA-PD estimate of the expected claim expenses, administrative expenses, and profit to cover the plan liabilities of the defined standard benefit or a basic benefit that is actuarially equivalent to the defined standard benefit (i.e. the pink portions of Exhibit 1.1) for a member with a Part D risk score of 1.00.
- Basic Premium is the 1.00 Bid for the PDP or MA-PD less the national average bid plus the national base beneficiary premium, where:
- Base Beneficiary Premium is 25.5% of (National Average Bid + National Average Value of Federal Reinsurance).
- The Direct Subsidy is then equal to the 1.00 Bid multiplied by the risk score, less the Basic Premium.

Table 1 shows a hypothetical example for ABC MA-PD Plan:

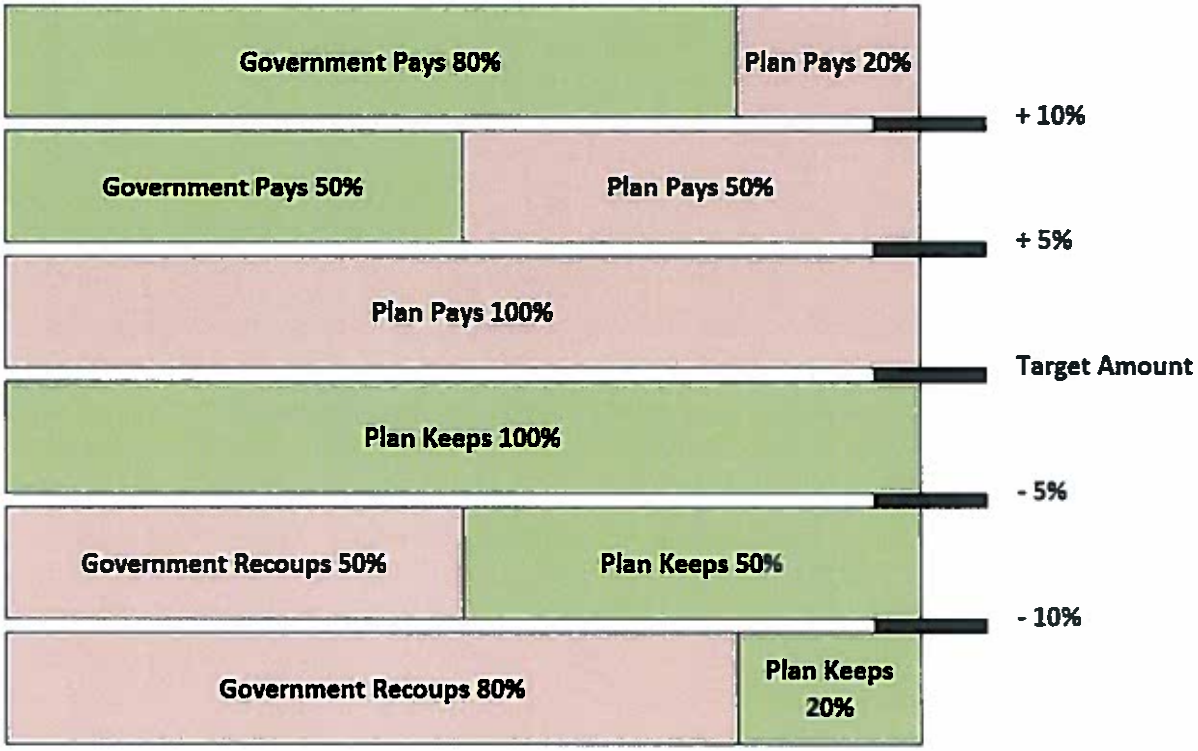
Table 1 Plan ABC Part D Bid Calculation of Direct Subsidy		
a.	Expected Part D Risk Score for Covered Population	1.05
b.	ABC Estimated Cost to Cover Defined Standard Benefit	$57.00
c.	ABC Non-Benefit expenses	$14.00
d.	ABC Target Profit (5.0%)	$3.74
e.	Basic Bid (b+c+d)	$74.74
f.	Basic Bid at 1.00 (e/a)	$71.18
g.	National Average Bid	$61.08
h.	National Base Beneficiary Premium	$35.63
i.	Basic Premium* (f-g+h)	$45.73
j.	Direct Subsidy (e-i)	$29.01

*Ignoring premium rounding

Risk Corridor

Originally designed as a means to encourage Part D sponsors to participate in the program, CMS established a risk-sharing mechanism where plans that experienced actual claim costs that were significantly different from the expected values filed in Part D bids would share in gains or losses on a pro-rata basis with CMS. This was called the "risk corridor", and has remained in place since 2006 (although the specific parameters changed once). The thresholds defining when risk sharing occurs increased in 2008 and have stayed the same ever since, even though CMS has had the authority to increase the threshold percentages further since 2012.

The graphic below shows the current risk corridor provisions, which have been in place since 2008.


Government Pays 80%
Plan Pays 20%
+ 10%
Government Pays 50%
Plan Pays 50%
+ 5%
Plan Pays 100%
Target Amount
Plan Keeps 100%
- 5%
Government Recoups 50%
Plan Keeps 50%
- 10%
Government Recoups 80%
Plan Keeps 20%

Wakely

Attachment B

At the request of the National Community Pharmacists Association (NCPA), Wakely Consulting Group, LLC (Wakely) has estimated the financial impact of companion House and Senate bills H.R. 1038/S. 413 ("Improving Transparency and Accuracy in Medicare Part D Spending Act") on the federal government over 2018 through 2027. The bills propose to prohibit retroactive reductions in claim payments by Part D sponsors.

The purpose of our analysis is to estimate the financial impact to the Centers for Medicare and Medicaid Services (CMS), considering only reductions in Part D payments made directly to pharmacies (i.e. manufacturer rebates are excluded). Use of these estimates may not be appropriate for other purposes.

Long-term projections over many years, such as those presented here, are inherently uncertain due to the length of the projection. In addition, our results are highly dependent on the assumptions made, so readers of this report should be familiar with the assumptions described below when evaluating results.

Below we describe the results of our analysis and describe the method and assumptions used.

Impact of H.R. 1038/S. 413 on CMS Payments Under Part D

Over 2018 through 2027, we estimate that the elimination of $125.9B in Part D retrospective payment reductions (a portion of direct and indirect remuneration or "DIR") will save the federal government $3.4B in Part D payments made to plan sponsors if H.R. 1038/S. 413 is implemented beginning January 1, 2018. This excludes the estimated impact of risk corridor settlements. The primary driver of this savings is payments related to the Part D federal reinsurance program. Table 1 shows the changes in CMS Part D payments by year and by component of the Part D program.

Table 1 - Impact of H.R. 1038/S. 413 on CMS Part D Payments Assuming a Shift of Pharmacy DIR to POS

2018 through 2027 Amounts in Billions					
Year	Direct Subsidy	Low-Income Premium Subsidy	Low-Income Cost-Sharing Subsidy	Federal Reinsurance	Total
2018	$0.0	$0.0	($0.6)	($0.8)	($1.4)
2019	$1.7	$0.3	($0.7)	($0.9)	$0.4
2020	$1.6	$0.3	($0.7)	($1.0)	$0.2
2021	$1.6	$0.4	($0.8)	($1.1)	$0.1
2022	$1.6	$0.5	($0.9)	($1.3)	($0.0)
2023	$1.7	$0.6	($0.9)	($1.5)	($0.1)
2024	$1.6	$0.7	($1.0)	($1.6)	($0.3)
2025	$1.6	$0.8	($1.1)	($1.8)	($0.5)
2026	$1.6	$0.9	($1.2)	($2.1)	($0.8)
2027	$1.5	$1.0	($1.3)	($2.2)	($1.0)
Total	**$14.6**	**$5.5**	**($9.1)**	**($14.3)**	**($3.4)**

Table 1 shows that we expect CMS to spend less on federal reinsurance and low-income cost-sharing subsidies. In both cases, the presence of additional discounts contributes to lower total drug cost at the point-of-sale. This serves to decrease low-income cost-sharing subsidies as the amount of member cost-sharing as per the benefit plan decreases while low-income patient pay amounts remain relatively steady. The decrease in total drug cost at point-of-sale also lowers the amount of claim dollars in the catastrophic phase of the Part D benefit because accumulated claims and amounts accumulating towards the true out of pocket (TrOOP) catastrophic threshold are lower.

On the other hand, direct subsidy payments and low-income premium subsidy payments are both expected to be higher if H.R. 1038/S. 413 is implemented. This is primarily because Part D bids on average should increase slightly due to the way that the Part D bid form treats discounts less favorably than rebates from a plan pricing perspective.

The results in Table 1 are highly dependent on the assumptions underlying our calculations. These assumptions are described in detail in the "Method and Assumptions" section, below; however, highlights of key assumptions are listed below:

- Differences in federal spending are intended to reflect Part D program activity nationwide, with the exception of self-insured employer coverage of Part D benefits where retiree drug subsidies are paid.

- Only retrospective payments related to direct pharmacy payments are considered in relation to the shift towards point-of-sale price concessions, while manufacturer rebates are consistently treated on a retrospective basis, except where noted otherwise below (i.e. Table 2).
- Lost payment reductions for Part D plan sponsors are assumed to be replaced by increased discounts on a dollar-for-dollar basis in re-negotiated Pharmacy Benefit Manager contracts. This assumption was also applied to calendar year 2018, despite delays in PBM negotiations that may occur given an assumed effective date of 1/1/2018.
- Retrospective payment reductions are 24% total gross drug costs prior to any shift from retrospective to point-of-sale price concessions.
- Retrospective payment reductions to pharmacies are 15% of all retrospective payment reductions.
- Gross pharmacy claim costs increase at a rate of about 8.5%-10% annually.
- We assumed a Part D defined standard benefit, with adjustments for estimated increases in benefit parameters such as deductible, initial coverage limit, and TrOOP threshold.
- Low-income premium subsidy is about 24% of estimated national Part D basic premium.
- Many assumptions rely on projections from the 2017 Medicare Trustees report.
- The Wakely RxCalc model was used to price the impact of Part D claim components by year.

We would also note that we believe that the direction of our results is not likely to be impacted by fluctuations in some of our assumptions such as claim trend, Part D enrollment, and the percentage of total retrospective payment reductions shifting to point-of-sale. Fluctuations in these items will cause magnitude differences, however.

For example, if we were to consider a shift of 100% of total retrospective payment reductions to point-of-sale, then the magnitude of the results would increase significantly as shown in Table 2 below; however, the positive or negative direction for each component remains the same.

Table 2 - Impact of H.R. 1038/S. 413 on CMS Part D Payments
Assuming a Shift of All DIR to POS
2018 through 2027
Amounts in Billions

Year	Direct Subsidy	Low-Income Premium Subsidy	Low-Income Cost-Sharing Subsidy	Federal Reinsurance	Total
2018	$0.0	$0.0	($4.6)	($5.7)	($10.3)
2019	$12.3	$1.8	($4.9)	($6.5)	$2.7
2020	$11.7	$2.4	($5.4)	($7.3)	$1.4
2021	$11.7	$3.0	($5.7)	($8.3)	$0.6
2022	$11.7	$3.6	($6.2)	($9.4)	($0.4)
2023	$11.8	$4.2	($6.7)	($10.7)	($1.4)
2024	$11.7	$4.9	($7.2)	($12.0)	($2.6)
2025	$11.8	$5.7	($7.8)	($13.5)	($3.9)
2026	$11.6	$6.5	($8.5)	($15.0)	($5.4)
2027	$11.3	$7.2	($9.0)	($16.3)	($6.9)
Total	**$105.5**	**$39.3**	**($66.0)**	**($104.9)**	**($26.0)**

Part D Risk Sharing Projection

The Part D program has maintained a risk sharing mechanism where results outside of specified risk corridors are shared between Managed Care Organizations (MCO) offering Part D and CMS. Beginning in 2012, CMS has the authority to widen these corridors or decrease the percentage share of risk borne by CMS; however, the parameters have not changed from 2012 through the 2018 contract year. Whether a Part D risk sharing payment is made (i.e. CMS pays the MCO or the MCO pays CMS) depends on the accuracy of the pricing submitted by the MCO in the original bid filing.

Due to the potential for CMS to alter risk corridors and risk sharing percentages as well as the significant uncertainty of projecting pricing accuracy, it is very challenging to project future risk sharing payments. For this reason, we have excluded risk sharing projections from the main results presented in the Impact section.

In considering the potential impact of the elimination of retroactive reductions to pharmacy payments on Part D risk sharing settlements, we examined historical risk sharing amounts released by CMS indicating that the program has typically resulted in payments to CMS from plan sponsors. Therefore, we developed estimates assuming that similar "favorable" plan experience in aggregate would to continue to occur. Please note that this is supported by

projections in the 2017 Medicare Trustees report, which projects net payables to CMS every year through 2026.

Our projection of the impact of H.R. 1038/S. 413 on risk sharing resulted in a reduction in the payable amounts to CMS from plan sponsors. This is shown in Table 3 as an increase in CMS expense.

Table 3 - Impact of H.R. 1038/S. 413 on CMS Part D Payments Assuming a Shift of Pharmacy DIR to POS

2018 through 2027 Amounts in Billions Including Risk Sharing Payments			
Year	Total Excluding Risk Sharing	Risk Sharing	Total
2018	($1.4)	$0.1	($1.3)
2019	$0.4	$0.1	$0.6
2020	$0.2	$0.2	$0.4
2021	$0.1	$0.2	$0.3
2022	($0.0)	$0.2	$0.2
2023	($0.1)	$0.2	$0.1
2024	($0.3)	$0.2	($0.1)
2025	($0.5)	$0.3	($0.3)
2026	($0.8)	$0.3	($0.5)
2027	($1.0)	$0.3	($0.6)
Total	($3.4)	$2.2	($1.2)

Method and Assumptions

In this section, we describe the process used and assumptions made in estimating impact of H.R. 1038/S. 413 on CMS Part D payments over 2018 through 2027. In general, we projected Part D claims and CMS payments under two scenarios – current conditions and an assumption that H.R. 1038/S. 413 is implemented and applies to only pharmacy-related price concessions.

Starting Base Data

It is our intent to model the aggregate Part D claims and CMS payments related to all Medicare Advantage and Prescription Drug Plan (PDP) sponsors nationwide. Part D claims related to self-insured employer sponsored coverage is excluded.

We developed starting costs for 2016 as follows:

- We began with 2015 nationwide drug costs of $137.4B and total direct and indirect remuneration (DIR) of $23.6B as reported in the January 19, 2017 CMS news release "Medicare Part D – Direct and Indirect Remuneration (DIR)".
    - We calculated an allowed drug cost PMPM (i.e. before cost-sharing) using Part D enrollment from the 2017 Trustees report.
    - We trended this 2015 allowed drug cost PMPM to 2016 based on the observed change in gross drug costs from 2014 to 2015 from the January 19, 2017 CMS news release.
    - We fit this estimated 2016 national allowed drug cost PMPM to detailed Wakely Part D claim data for calendar year 2016.
    - In the Wakely data, we identified drugs as specialty, brand, and generic based on Wakely studies and external data sources.
    - We assumed that the beginning costs reflected the same distribution of low-income and non-low-income members as found in the 2017 Medicare Trustees report. The distributions by specific low-income category was developed from three sources:
        - Enrollment projections in the 2017 Medicare Trustees report – used to develop the percentage of low-income members that are partial duals
        - 2015 Medicare Limited Data Set (LDS) data – used to develop an estimated percentage of members with an institutional status
        - Wakely internal data – was used to develop the percentage of low-income members that are above or below the federal poverty limit

Appendix A provides a summary of starting 2016 utilization, costs per script, and allowed costs PMPM by generic, brand, and specialty drug type.

Our starting cost model also required other assumptions in addition to claim costs. These included the following:

- RxHCC Risk score of 1.00. We believe an assumption of 1.00 is an accurate representation of nationwide Part D plan sponsors because publicly available data from 2014 and 2015 showed a nationwide average very close to 1.00 in both years.
- Non-benefit expenses (excluding health insurance provider fees) equal to 9% of required revenue, prior to the shift towards point-of-sale price concessions. This is based on publicly available minimum loss ratio filings.
- Health insurance provider fees equal to 1.6% of required revenue, prior to the shift towards point-of-sale price concessions, in 2018 and 1.5% in 2019 onwards.
- Profit margin equal to 5% of required revenue on a pre-sequestration basis, prior to the shift towards point-of-sale price concessions. This is based on a nationwide post-sequestration average of about 3% profit, as reported in minimum loss ratio filings.

- The 2018 national average bid of $57.93 and base beneficiary premium of $35.02, as reported by CMS in the July 31, 2017 rebate reallocation announcement.

Projection by Year through 2027

Numerous assumptions were needed in order project CMS Part D payments and claim amounts by year through 2027.

The following projection assumptions were used:

- **Enrollment**. Total enrollment was based on projections in the 2017 Medicare Trustees report. Our analysis includes individual and employer group waiver program (EGWP) enrollees, but excludes retiree drug subsidy beneficiaries. The distribution of non-low-income and low-income members was assumed to vary based on the enrollment projections through 2026 in the 2017 Medicare Trustees report. This includes amounts used to determine the distribution of enrollment by low-income category from the 2017 Medicare Trustees report. Enrollment amounts for 2027 were assumed to be the same as those for 2026.

- **Allowed Cost Trend**. Total drug costs (before cost-sharing) were trended based on several components. First, we estimated the impact of patent expirations based on Wakely analysis of 2017-2018 anticipated expirations. This trend was held the same by year. Second, we trended brand, generic, and specialty drugs at annual rates based on Wakely drug trend studies that excluded the impact of brand patent expirations. We separated costs for high-cost Hepatitis C drugs from other specialty drugs, and applied a flat 1.0 trend factor to these drugs. Induced utilization adjustments were not made in the projections. Trend factors by drug type and year are shown in Appendix B. These trend factors include the impact of projected brand patent expirations by year.

  Overall, the annual allowed drug trend was about 8.5%-10%. The generic dispensing rate (GDR) increased marginally each year. Table 4 shows the projected GDR by year.

Table 4 - Generic Dispensing Rate

2018 through 2027	
Year	Generic Dispensing Rate
2018	84.0%
2019	84.6%
2020	85.2%
2021	85.8%
2022	86.4%
2023	86.9%
2024	87.4%
2025	87.9%
2026	88.4%
2027	88.8%

- **Part D Benefit Parameters**. The Part D Defined Standard benefit design was used for all years. Pricing in 2019 and 2020 reflects the incremental reduction in beneficiary cost-sharing as specified in the Affordable Care Act. Values for the Part D deductible, initial coverage limit, and attachment point for the maximum out-of-pocket threshold were trended at an annual rate of 4%. Catastrophic and low-income copayment amounts were also trended at 4% annually, with the exception of copayments amounts for the low-income category of members with annual spend below the federal poverty limit, which were trended at 2% annually. The national average bid amount (NABA) and base beneficiary premium (BBP) were projected assuming decreasing marginal reductions each year. In addition, we adjusted the NABA and BBP to recognize the impact of increased discounts if H.R. 1038/S. 413 is implemented, and only pharmacy DIR is affected. Table 5 shows the NABA and BBP by year.

Table 5 - National Average Bid and Base Beneficiary Premium Assumptions

2018 through 2027				
Year	Current Conditions		H.R. 1038/S. 413 Implemented	
	NABA	BBP	NABA	BBP
2018	$57.93	$35.02	$57.93	$35.02
2019	$55.29	$36.02	$58.94	$36.61
2020	$53.01	$37.11	$56.33	$37.61
2021	$51.07	$38.28	$54.26	$38.74
2022	$49.41	$39.53	$52.48	$39.95
2023	$48.00	$40.84	$50.94	$41.22
2024	$46.81	$42.21	$49.67	$42.57
2025	$45.83	$43.63	$48.61	$43.97
2026	$45.03	$45.10	$47.71	$45.40
2027	$44.40	$46.61	$46.99	$46.90

The low-income premium subsidy amount by year was calculated as 24% of the estimated Part D basic premium amount projected for each year. This assumption is based on data in the publicly available 2015 minimum loss ratio filings. Note that the 24% factor considers both the relationship of the LIPSA to the national average BBP as well as the percentage of Part D beneficiaries nationwide who are low income.

- **Retroactive Payment Reductions**. We projected the retroactive payment reductions by year as 24% of projected allowed drug costs. For scenarios where we modeled the impact of H.R. 1038/S. 413, we assumed that PBM discounts would increase by the same dollar amount as the eliminated retroactive reductions to pharmacies. As discussed earlier, reductions related only to direct pharmacy payments were assumed to be 15% of total reductions. In other words, the increased discount under H.R. 1038/S. 413 was equal to:

(total allowed cost) x 24% x 15%

We relied on the July 2017 Milliman report, "Value of Direct and Indirect Remuneration (DIR): Impact on Medicare Part D Prescription Drug Plan (PDP) Program Stakeholders", for assumptions regarding payment reductions as a percentage of allowed drug costs as well as the assumed percentage attributable to pharmacies.

- **Part D Risk Sharing.** We examined historical net risk sharing payments released by CMS and observed that in aggregate across all organizations, the risk sharing program typically results in a payable to CMS from plan sponsors. Therefore, we developed estimates assuming that similar "favorable" plan experience in aggregate would to continue to occur. The estimated risk sharing amount is highly speculative given that we do not know if this pattern will continue or what specifically was driving it in the past (i.e. lower-than-expected claims costs, higher-than-expected rebates or other DIR, some combination of the two, population shifts among plans, or other factors).

  In order to develop factors to estimate this favorable plan experience, we relied on the following:

  - Aggregate risk corridor amounts from the 2015 CMS plan payment data
  - The CMS re-release of the 2015 national average bid amount weighted by concurrent year February 2015 enrollment
  - An assumed target loss ratio of 84% based on publicly available minimum loss ratio filings

  In using this information, we estimated that a risk corridor ratio (actual / expected) of 0.85 would have produced the aggregate risk sharing transfer across all carriers in 2015. This ratio was then used to develop the three scenarios of risk sharing estimates shown in Table 6, which vary depending on the assumed driver of plan sponsors' overall favorable experience. Scenario 3 represents our best estimate and is therefore included in the Table 3 summary results, above.

Table 6 - Part D Risk Sharing Scenarios by Driver

Year	Favorable Experience Due to: Scenario 1: Lower-than-Expected Claims	Scenario 2: Higher-than-Expected DIR	Scenario 3: An Equal Combination of Lower Claims and Higher DIR
2018	$0.0	$0.2	$0.1
2019	$0.1	$0.2	$0.1
2020	$0.1	$0.3	$0.2
2021	$0.1	$0.3	$0.2
2022	$0.1	$0.3	$0.2
2023	$0.1	$0.4	$0.2
2024	$0.1	$0.4	$0.2
2025	$0.1	$0.5	$0.3
2026	$0.1	$0.5	$0.3
2027	$0.2	$0.5	$0.3
Total	$0.9	$3.7	$2.2

Disclosures

Tim Courtney and Drew McStanley are financially independent and free from conflict concerning all matters related to performing the actuarial services underlying this analysis. In addition, Wakely is organizationally and financially independent from NCPA.

The assumptions and resulting estimates included in this report are inherently uncertain. Users of the results should be qualified to use and understand the results their inherent uncertainty. Actual results may vary, potentially materially, from our estimates. Wakely does not warrant or guarantee that projected results in this report will be realized. It is the responsibility of the organization receiving this output to review the assumptions carefully and notify Wakely of any potential concerns.

We have relied on others for data and assumptions used in this report. We have reviewed the data for reasonableness, but have not performed any independent audit or otherwise verified the accuracy of the data/information. If the underlying information is incomplete or inaccurate, our estimates may be impacted, potentially significantly.

Our work on this report conforms to the following Actuarial Standards of Practice (ASOP) issued by the Actuarial Standards Board:

- ASOP #5, "Incurred Health and Disability Claims"
- ASOP #23, "Data Quality"
- ASOP #41, "Actuarial Communications"

Appendix A
2016 Base Utilization and Costs

	Utilization per 1000	Allowed PMPM	Unit Cost
Low-Income			
Brand	3,019.7	$77.06	$306
Generic	21,061.4	$39.29	$22
Specialty			
High-Cost Hepatitis C Drugs	5.1	$12.35	$28,830
All Other Specialty	367.9	$54.86	$1,789
Total Specialty	373.1	$67.21	$2,162
All Drug Types	24,454.2	$183.57	$90
Non Low-Income			
Brand	2,175.8	$56.27	$310
Generic	21,461.0	$40.85	$23
Specialty			
High-Cost Hepatitis C Drugs	1.9	$4.63	$29,655
All Other Specialty	121.7	$34.68	$3,419
Total Specialty	123.6	$39.31	$3,816
All Drug Types	23,760.4	$136.43	$69
Total Population			
Brand	5,195.5	$133.34	$308
Generic	42,522.4	$80.14	$23
Specialty			
High-Cost Hepatitis C Drugs	7.0	$16.99	$29,050
All Other Specialty	489.7	$89.54	$2,194
Total Specialty	496.7	$106.53	$2,574
All Drug Types	48,214.6	$320.00	$80

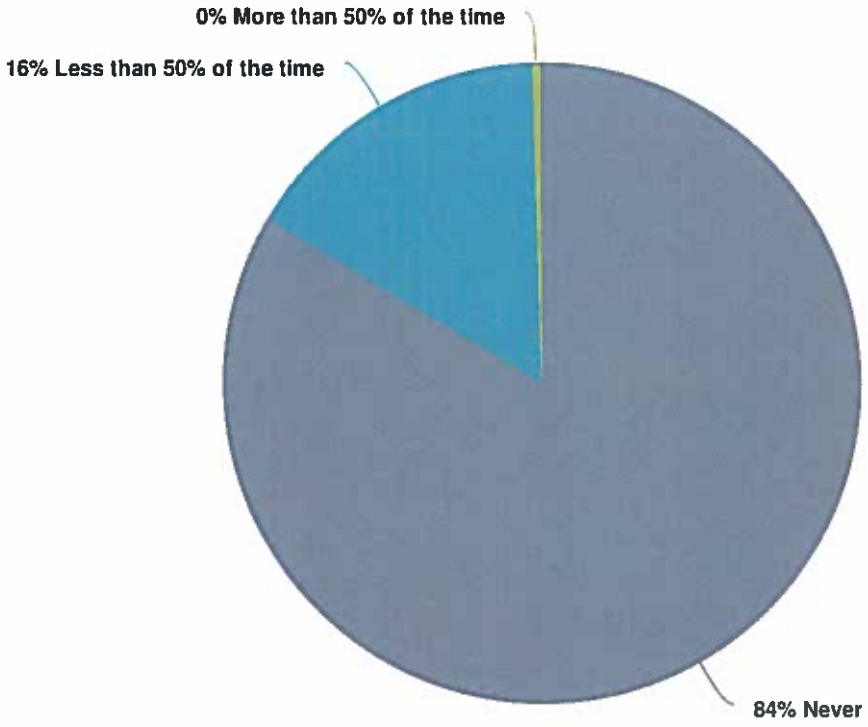
Appendix B
Assumed Trend Factors by Member Type and Drug Type

	Utilization Trend Factor				Unit Cost Trend Factor			
			Specialty				Specialty	
	Brand	Generic	High-Cost Hepatitis C Drugs	All Other Specialty	Brand	Generic	High-Cost Hepatitis C Drugs	All Other Specialty
Low-Income								
2016 to 2018	1.069	0.824	1.000	0.919	1.131	1.119	1.000	1.000
2016 to 2019	1.093	0.843	1.000	0.940	1.155	1.142	1.000	1.021
2016 to 2020	1.118	0.862	1.000	0.961	1.179	1.167	1.000	1.043
2016 to 2021	1.143	0.882	1.000	0.983	1.204	1.191	1.000	1.065
2016 to 2022	1.169	0.902	1.000	1.005	1.230	1.216	1.000	1.088
2016 to 2023	1.196	0.922	1.000	1.028	1.256	1.242	1.000	1.111
2016 to 2024	1.223	0.943	1.000	1.052	1.282	1.268	1.000	1.134
2016 to 2025	1.251	0.965	1.000	1.076	1.309	1.295	1.000	1.158
2016 to 2026	1.279	0.987	1.000	1.100	1.337	1.322	1.000	1.182
2016 to 2027	1.308	1.009	1.000	1.125	1.365	1.350	1.000	1.207
Non-Low-Income								
2016 to 2018	1.036	0.830	1.000	0.908	1.083	1.058	1.000	1.011
2016 to 2019	1.046	0.839	1.000	0.918	1.098	1.072	1.000	1.026
2016 to 2020	1.057	0.848	1.000	0.927	1.113	1.087	1.000	1.040
2016 to 2021	1.069	0.857	1.000	0.937	1.129	1.103	1.000	1.054
2016 to 2022	1.080	0.866	1.000	0.947	1.144	1.118	1.000	1.069
2016 to 2023	1.091	0.875	1.000	0.957	1.160	1.134	1.000	1.084
2016 to 2024	1.103	0.884	1.000	0.967	1.176	1.149	1.000	1.099
2016 to 2025	1.114	0.893	1.000	0.977	1.193	1.165	1.000	1.115
2016 to 2026	1.126	0.902	1.000	0.987	1.210	1.182	1.000	1.130
2016 to 2027	1.138	0.912	1.000	0.997	1.226	1.198	1.000	1.146

Attachment C

Report for Survey of DIR Fees Imposed on Pharmacies

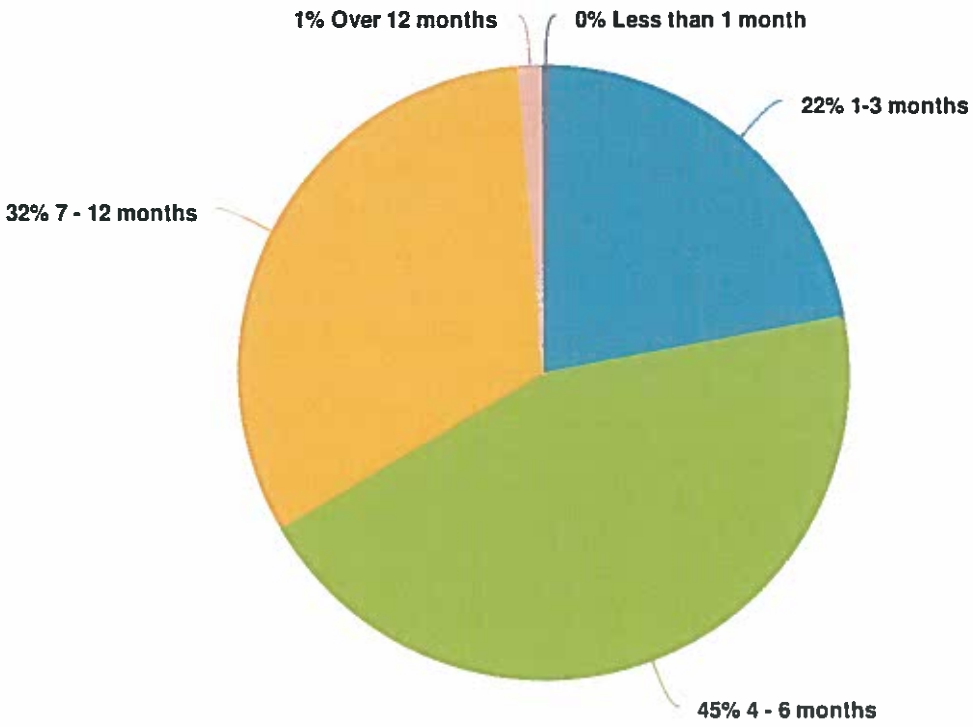
1. When you serve a Part D patient, how often do you know at point of sale exactly what your final reimbursement will be?



Value	Percent	Responses
Never	83.5%	198
Less than 50% of the time	16.0%	38
More than 50% of the time	0.4%	1

Totals: 237

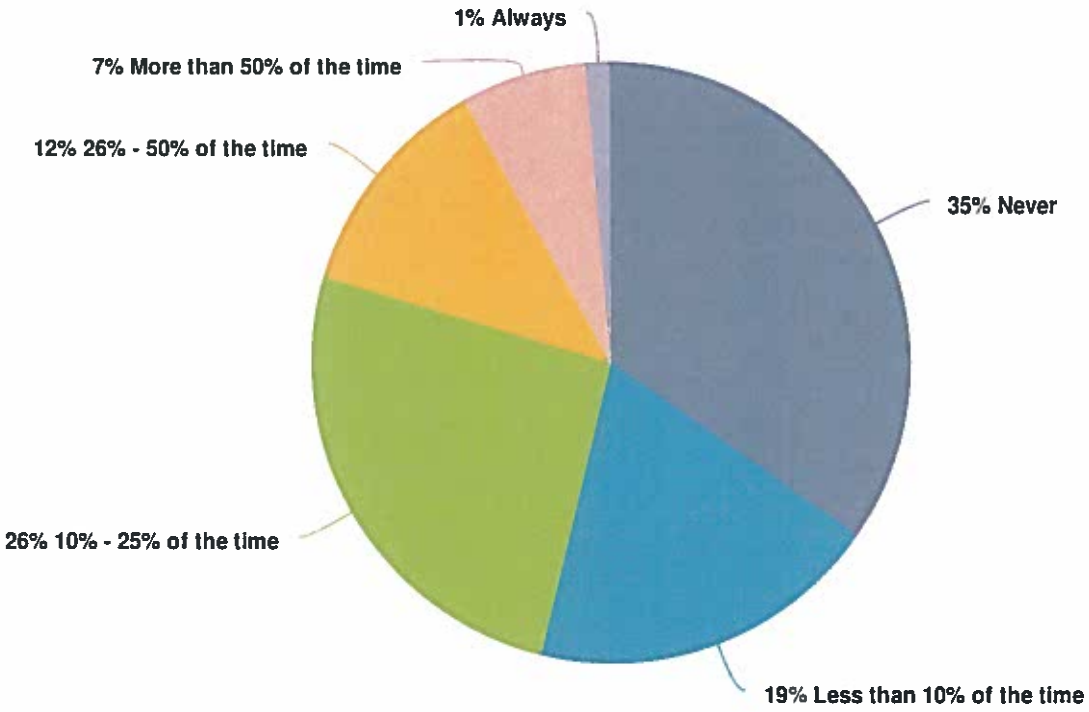
2. If you don't know your reimbursement at point of sale for a prescription due to a DIR charge, on average how long after is it before you know your final reimbursement?



Value	Percent	Responses
Less than 1 month	0.4%	1
1-3 months	21.6%	51
4 - 6 months	44.5%	105
7 - 12 months	32.2%	76
Over 12 months	1.3%	3

Totals: 236

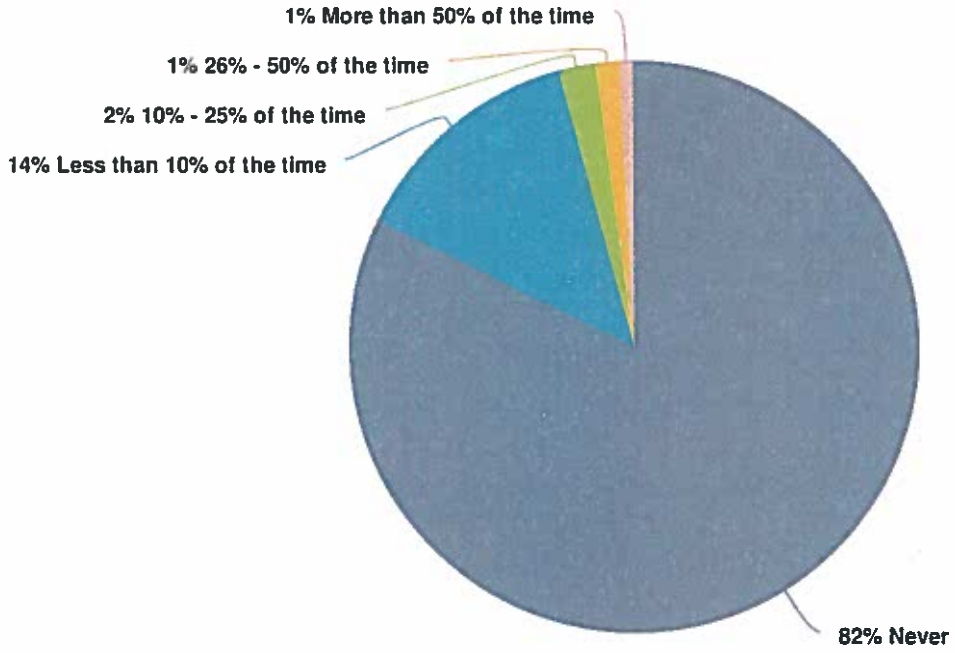
3. When you receive a payment reconciliation statement showing DIR fees charged to your pharmacy for Part D prescriptions, how often are the DIR charges itemized to SPECIFIC PRESCRIPTION CLAIMS?



Value	Percent	Responses
Never	34.7%	82
Less than 10% of the time	19.1%	45
10% - 25% of the time	25.8%	61
26% - 50% of the time	12.3%	29
More than 50% of the time	6.8%	16
Always	1.3%	3

Totals: 236

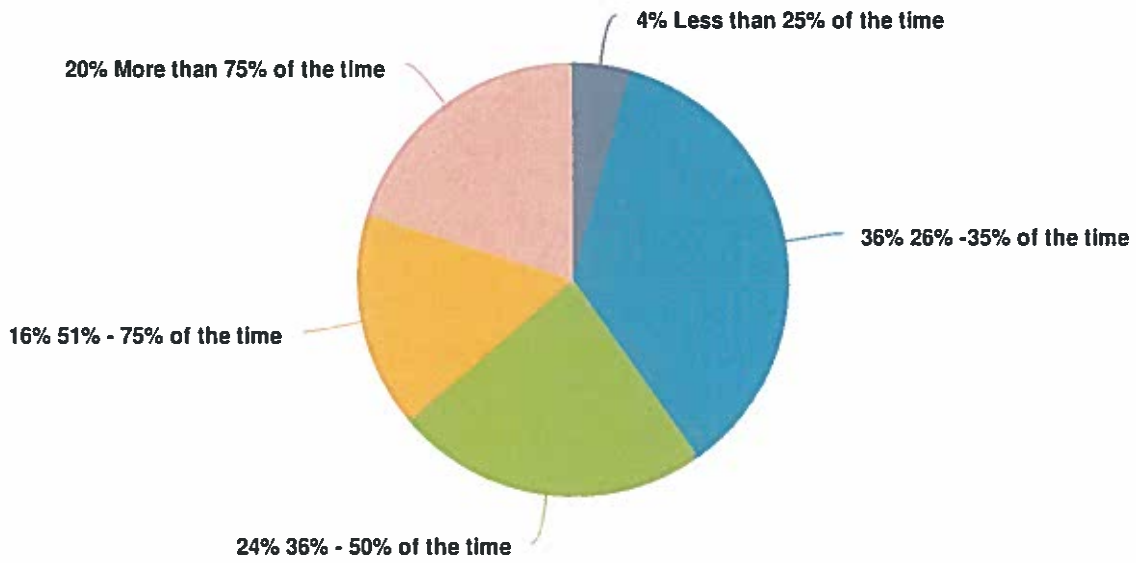
4. When you receive a reconciliation statement showing DIR fees charged to your pharmacy for Part D prescriptions, how often do you receive substantiating data relating DIR FEES to SPECIFIC PATIENT HEALTH OUTCOMES?



Value	Percent	Responses
Never	82.3%	195
Less than 10% of the time	13.5%	32
10% - 25% of the time	2.1%	5
26% - 50% of the time	1.3%	3
More than 50% of the time	0.8%	2

Totals: 237

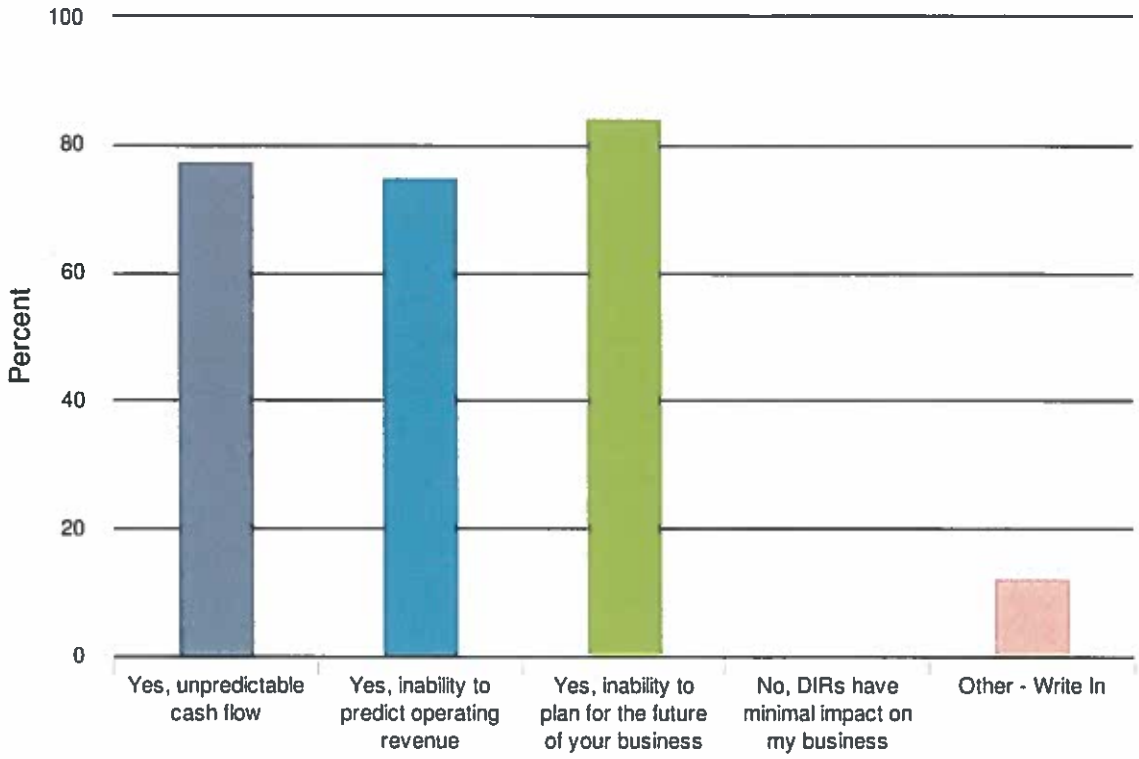
5. After DIR fees are deducted from your pharmacy reimbursements, how often is the pharmacy's reimbursement for a prescription below the pharmacy's total dispensing cost (acquisition cost plus cost of dispense) for that prescription?



Value	Percent	Responses
Less than 25% of the time	4.3%	10
26% -35% of the time	35.9%	84
36% - 50% of the time	23.5%	55
51% - 75% of the time	16.2%	38
More than 75% of the time	20.1%	47

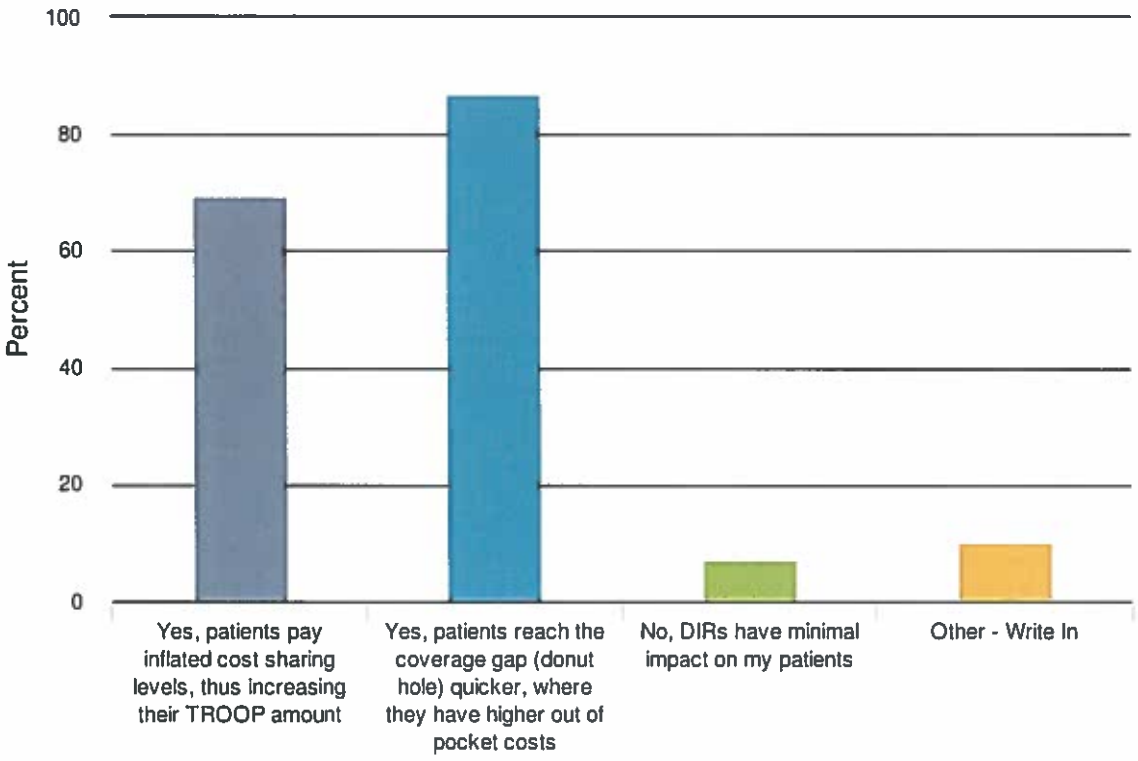
Totals: 234

6. Are DIR fees affecting your ability to manage the business operations of your pharmacy? (Mark all that apply)



Value	Percent	Responses
Yes, unpredictable cash flow	77.6%	184
Yes, inability to predict operating revenue	75.1%	178
Yes, inability to plan for the future of your business	84.4%	200
No, DIRs have minimal impact on my business	0.4%	1
Other - Write In	12.2%	29

7. Are DIR fees affecting your patients' access to prescription medication? (Mark all that apply)



Value	Percent	Responses
Yes, patients pay inflated cost sharing levels, thus increasing their TROOP amount	69.1%	163
Yes, patients reach the coverage gap (donut hole) quicker, where they have higher out of pocket costs	86.9%	205
No, DIRs have minimal impact on my patients	7.2%	17
Other - Write In	10.2%	24

Attachment D

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

NCPA DIR Survey Profile

Part D patients comprise a significant portion of community pharmacists' patient base. According to the most recent NCPA Digest benchmarking survey, the mean percentage of total prescriptions dispensed under Medicare Part D by respondents is 36%. The NCPA Digest also reports that the mean total number of Part D prescription filled by a community pharmacy in the past year was 21,508 prescriptions.

A December 2017 survey of members of the National Community Pharmacists Association – independent pharmacy owners – provided the following data on the effects of Medicare Part D direct and indirect remuneration fees on community pharmacies across the country:

• A majority of pharmacy owners say unpredictable DIR fees are hindering their ability to manage the business operations of their pharmacy.
- 78% cite unpredictable cash flows
- 75% cite inability to predict operating revenue
- 84% cite inability to plan for the future of the business

• A majority of pharmacy owners say DIR fees are hindering patient access to prescription medications.
- 69% cite inflated cost-sharing levels, thus increasing their patients' True Retail Out-of-Pocket amount.
- 87% cite patients reaching the Part D coverage gap more quickly, where they have higher out-of-pocket costs

• 84% of community pharmacy owners say they NEVER know at point-of-sale what their final reimbursement will be when serving a Medicare Part D patient.

• It frequently takes months for pharmacy owners to learn their final reimbursement amount. When serving a Medicare Part D patient, 77% of respondents say it normally takes 4-12 months before they learn their final reimbursement.

• DIR charges are not consistently itemized to prescription claims, making it difficult for pharmacy owners to trace DIR fees to specific claims. 35% of respondents say DIR fees are NEVER itemized to specific claims. Another 45% of respondents say DIR fees are itemized to specific claims less than 25% of the time.

• PBMs often say DIR fees are linked to patient outcomes and pharmacy quality, but they are not sharing that outcomes data with pharmacy owners. 82% of pharmacy owners say they NEVER receive information relating the DIR fees they are charged to specific patient outcomes or quality measures.

• After reconciliation, pharmacy owners often find that the reimbursement they receive is less than the pharmacy's dispensing costs (acquisition plus cost to dispense).
- 36% say reimbursement is less than costs more than 50% of the time
- 60% say reimbursement is less than costs 25-50% of the time

SELECT EXAMPLES CITED BY RESPONDENTS:

• How pharmacy retroactive DIRs fees are affecting patients

- Patient refused to take Tetracycline for C. difficile infection due to high co-pay
- Patient unable to pay co-pay while in doughnut hole refuse to take the drug

• Reimbursements leaving pharmacies upside-down

- 10/27/17 rx for Oxymorphone ER 30mg tabs; #60 tabs: Acquisition cost $262.34; Third Party $399.94: Copay $1.20; total reimbursement $401.14 DIR Fee $164.42 Net reimbursement $236.72 for a loss of $25.62
- 11/16/17 rx for Metformin ER 1000mg #60 tabs: acq cost $455.18; third party $530.25; copay $10.01: total reimbursement $540.26. DIR fee $281.01 New total reimbursement $259.25 ($195.93 below our acq)
- Dispensed a medication which cost $1992.45. At adjudication we were expecting total payment of $1902.75 for a net loss of $89.70. Was charged a post adjudication amount of $862.63 which equated to a net loss of $952.33.
- Dispensed a medication which cost $604.39. At adjudication we were expecting total payment of $669.41 for a net profit of $65.02. Was charged a post adjudication amount of $349.44 which equated to a net loss of $284.42.
- ENTACAPONE 200MG #120 TABS, Insurance + CoPay=$187.74 Less DIR Fees of $148.30: Total Paid $39.44, Medication Cost $207.84; Pharmacy Loss $168.40
- FILLED AN RX FOR TOTAL REIMBURSMENT OF $0.27(7 CENTS FOR THE DRUG AND 20 CENTS FOR THE FEE). LATER ON A DIR FEE OF $5.00 WAS ENACTED.
- FOR A GENERIC ADDERALL RX COSTING $367 IT WAS ADJUDICATED FOR $600. 90 DAYS LATER THEY THEY ENACTED A DIR ON THAT RX OF $542.

• How PBMs handle DIRs (name of PBM is redacted)

- [redacted] shows a high profit margin at POS then does the "true up" months later and reduces the payment to right below cost.
- [redacted]'s DIR fees based on factors we CANNOT control and you do not know for 6 months to a year what the recoupment is.
- [redacted] takes back either $8.50 or $9.50 on every Part D script even if we were reimbursed $2 or $3 for the script.
- [redacted] just takes a % per rx. About $1500 from Dec 2016 to Oct 2017...it has nothing to do with patient adherence or safety.
- [redacted] charges $5 for a DIR fee per claim even if drug cost 0.30 and copay was only $1.59
- I have only 4 [redacted] patients my estimated DIR fee for the coming year is over $2100

For more information, contact NCPA Health Care Economist Leon Michos at leon.michos@ncpanet.org.