



# Tennessee Pharmacists Association

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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:

On behalf of the members of the Tennessee Pharmacists Association (TPA), I greatly appreciate the opportunity to provide insight and proposed solutions, from the perspective of practicing pharmacists in Tennessee, on the CMS Proposed Rule CMS-4182-P. As the only 501(c)6 professional organization in Tennessee representing approximately 3,000 pharmacists, student pharmacists, pharmacy technicians, and associate members in all pharmacy practice areas, TPA's mission is to advance, protect, and promote high-quality pharmacist-provided patient care in Tennessee. TPA would like to acknowledge and thank CMS for this opportunity to comment on the agency's 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.<sup>1</sup>

This Proposed Rule addresses several extremely important issues facing our pharmacists and the patients they serve every single day. TPA applauds CMS' ongoing commitment to addressing these patient-centric, pharmacy-related issues in order to ensure that our patients here in Tennessee maintain uninterrupted access to pharmacist-provided care, which will solidify the future sustainability of care and pharmacy practice moving forward.

## **Fully Integrate Pharmacists To Promote Appropriate and Efficient Utilization of Prescription Drugs**

*TPA strongly advocates for changes at the federal level to formally recognize pharmacists as providers under the Social Security Act and within CMS. Fully integrating pharmacists as providers will drive more appropriate and efficient medication selection and use, increase prescription drug-related health outcomes, decrease overall costs of care, and ensure that patients have access to pharmacist-provided care and services.*

Emphasizing appropriate prescription drug use and incentivizing providers who work with patients to improve health outcomes through optimal prescription drug use will lead to better patient care and

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<sup>1</sup> 82 Fed. Reg. 56,336 (Nov. 28, 2017).

decreased overall costs to the health care system. Pharmacists consider the costs (financial and the potential for side effects) and benefits (health outcomes) of a medication when assessing the appropriateness of a prescription, conducting a comprehensive medication review, or examining a coverage policy for a class of medications. Pharmacists, in all practice settings, are often the primary member of the healthcare team who is able to add the financial layer of analysis to patient medication regimens. Hospital pharmacists lead efficient formulary development,<sup>2</sup> community pharmacists make recommendations for cost effective therapeutic substitutions,<sup>3</sup> and managed care pharmacists design coverage policies to guide effective medication use at the population level, but also allow for patients with unique needs to get the best medication for them.<sup>4</sup> TPA broadly encourages CMS and other policy makers to recognize the value that pharmacists bring to the continuum of medication use. While efficient medication selection is important to controlling the growing costs of health care, it is also important to consider the value medications bring to healthcare. When taken correctly, medications provide the most effective way to manage chronic conditions, prevent future, and costly, complications, and even cure some diseases. Unfortunately, medications are often not taken as directed—a problem that leads to costly complications and prevents medications from delivering on their promise for improved outcomes.<sup>5,6</sup> If medications do not deliver on their potential for improved outcomes, their value significantly decreases. Pharmacists' medication management services are critical to ensuring patients use their medications correctly.<sup>7</sup> Investing in pharmacists' medication management services has been shown to significantly decrease overall healthcare costs.<sup>8,9</sup>

### **Reflect Pharmacy Price Concessions at the Point-of-Sale**

*TPA 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, TPA 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.*

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. TPA 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. TPA continues to advocate for such an approach and fully support CMS' proposal to do just that in the 2019 Proposed Rule.

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<sup>2</sup> <http://www.pharmacytimes.com/publications/health-system-edition/2017/september2017/hospital-formulary-management>

<sup>3</sup> <http://www.pharmacytimes.com/news/therapeutic-substitution-could-curb-skyrocketing-drug-costs>

<sup>4</sup> <http://www.amcp.org/InformationForTertiary.aspx?id=9045>

<sup>5</sup> [www.nehi.net/writable/publication\\_files/file/pa\\_issue\\_brief\\_final.pdf](http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf)

<sup>6</sup> [www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/)

<sup>7</sup> [www.accp.com/docs/positions/misc/improving\\_patient\\_and\\_health\\_system\\_outcomes.pdf](http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf)

<sup>8</sup> [www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/MP7-PSMP-Diabetes-JAPhA-Final%20Report.pdf](http://www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/MP7-PSMP-Diabetes-JAPhA-Final%20Report.pdf)

<sup>9</sup> [www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/201101\\_ImPACT\\_Depression\\_JAPhA.pdf](http://www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/201101_ImPACT_Depression_JAPhA.pdf)

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 TPA and the pharmacy community, but CMS and the Medicare Payment Advisory Commission (“MedPac”) for many reasons.<sup>10</sup> 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. 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 and pharmaceutical manufacturer rebates 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, the National Community Pharmacists Association (NCPA) commissioned a study of a proposed bill that would prohibit retroactive pharmacy payment reductions only on “clean claims” (those claims without any defect, impropriety, or fraud) in Medicare Part D by Wakely Consulting Group, a leading healthcare actuarial firm.<sup>11</sup> 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.

Of concern to TPA members, retrospective pharmacy concessions do not allow for pharmacies to account for profit at per prescription level. A pharmacy is reimbursed at the “negotiated price” absent retrospective pharmacy concessions and such reimbursement may be adequate and appropriate. Then, months later a large amount is withheld by a Sponsor or PBM suddenly making the reimbursement on the claim inadequate and perhaps lower than acquisition cost. The pharmacy is not able to forecast or model for this withholding, often not knowing the total DIR fee in advance and 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 by 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”). TPA vehemently disagrees. CMS is not inserting itself into negotiations between Sponsors and/or their PBMs and

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<sup>10</sup> See CMS **Medicare Part D – Direct and Indirect Remuneration (DIR) dated January 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>.

<sup>11</sup> The Wakely Consulting Group study estimating the final impact of companion House and Senate bill H.R. 1038/S. 413, the “Improving Transparency and Accuracy in Medicare Part D Spending Act,” available at <http://www.TPA.co/pdf/wakely-report.pdf>.

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 1<sup>st</sup> of each year and every seven days thereafter.<sup>12</sup> 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.<sup>13</sup> Sponsors and/or their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or pay structure they like just as pharmaceutical 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.

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 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: reimbursement to pharmacies based on “negotiated price” would be the lowest possible reimbursement and that could be “trued up” later to a higher amount in accordance with each Sponsor’s or its PBM’s contractual arrangement with the pharmacy.

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, the National Community Pharmacists Association (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 than 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

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<sup>12</sup> See 42 C.F.R. 423.520(c) and 42 C.F.R. 423.505(b)(21) respectively.

<sup>13</sup> See 42 C.F.R. 423.104 and 42 C.F.R. 423.120(b) respectively.

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 a lower Part D bid of post point-of-sale DIR amounts are favored over discounts amounts (i.e., dollar for dollar). A lower Part D bid typically translates into increase 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 in order 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.<sup>14</sup>

### **Implement Any Willing Pharmacy Standard Terms and Conditions and Better Defined Pharmacy Types**

*TPA greatly appreciates CMS continuing to recognize pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards. TPA 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.*

The “any willing pharmacy” provision found at Section 1860D-4(b)(10(A) of the Social Security Act is essential to 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. Tennessee statute currently contains an “any willing pharmacy” provision which ensures that patients in Tennessee enrolled in commercial and private plans have ongoing access to the pharmacy of their choice. This is a very important state law, but changes are needed at the federal level to ensure this same level of protection is afforded to all patients in federally regulated plans such as Medicare.

TPA 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). TPA urges CMS to codify this expectation in the final rule, and make very clear to 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. TPA 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. TPA members

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<sup>14</sup> 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\\_](http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0_).



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 PBM's 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, TPA greatly appreciates CMS acknowledging these concerns in the proposed rule while also recognizing the importance of upholding any willing pharmacy standard terms and conditions.

Further, TPA 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 "community pharmacy," Part D plan sponsors may not exclude them from Part D community networks. Many TPA member pharmacists offer additional services to patients including home delivery by mail, compounding, home infusion, or specialized services that focus on one or more specific disease states. Over the past years, TPA pharmacist members have shared numerous accounts of situations in which Part D plan sponsors and/or PBMs have informed community 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 have 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, TPA 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**

*TPA 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 pharmacists provide added services for their patients, one of which being the willingness to mail prescription refills to patients who may spend part of the year or the winter in another location. The pharmacist'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. TPA member pharmacists 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 pharmacists have been told that they must either cease and desist or otherwise risk being terminated from their pharmacy contract or register as a mail order pharmacy with the Part D plan sponsor/PBM 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 plan/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.<sup>15</sup> These same PBMs administer many of the Part D plans that were terminating pharmacies from Part D pharmacy networks due to their mail 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 rates will indeed distinguish between community pharmacies that offer some mail delivery from "true" mail order pharmacies—those which have no community presence and offer mail delivery at mail order rates. TPA is strongly supportive of this proposed definition and underlying policy.

### **Ensure Timely Access to Standard Terms and Conditions**

*TPA is strongly supportive of the proposed requirements that Part D plan sponsors must have standard terms and conditions developed and ready for distribution by September 15<sup>th</sup> and that Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request.*

TPA pharmacist members have expressed to CMS over the years their frustration that many times 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.

### **Appropriately Implement the Comprehensive Addiction and Recovery Act of 2016 Provisions**

*Prescription drug abuse continues to plague our state and our nation, and TPA is highly supportive of CMS' conservative and uniform approach to implement the Comprehensive Addiction and Recovery Act of 2016 provisions in Medicare Part D.*

TPA 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. Ensuring 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.

TPA also supports the exemption of Hospice, cancer, and long-term care ("LTC") patients from drug management programs. TPA asks 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.

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<sup>15</sup> The American Prospect, The Hidden Monopolies that Raise Drug Prices, Mar. 28, 2017, *available at* <http://prospect.org/article/hidden-monopolies-raise-drug-prices>.

TPA strongly supports prescriber agreement to implement a pharmacy lock-in and that any notices sent from plan sponsors or PBMs be approved by the Secretary. TPA understands 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 prescribers and pharmacies 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. TPA 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, TPA 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, TPA has learned of unfortunate hospital admissions. TPA 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. TPA feels 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.

TPA urges CMS remain vigilant in ensuring appropriate patient access. TPA strongly recommends 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**

*TPA is opposed to CMS' proposal to shorten the required transition days' supply in the Long-Term Care (LTC) setting to the same supply currently required in the outpatient setting. Changing the current requirement for a ninety-one to ninety-eight day supply of nonformulary drugs for patients transitioning from another health plan to only thirty days of medication is too drastic of a reduction.*

TPA 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 multiple 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, TPA 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.

### **Communications, Marketing Materials, and Activities**

*TPA believes that all information provided to beneficiaries should be inclusive, complete, and accurate to allow the beneficiary to make their own decisions regarding which plan to select and which pharmacy to use.*

TPA appreciates CMS' approach to narrow the definition of "marketing" in order to focus on materials and activities that aim to influence enrollment decisions. 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." Any attempts to use information to intentionally mislead beneficiaries when selecting a plan or choosing to utilize a specific pharmacy (including the use of the term "preferred") should be expressly prohibited.

### **Conclusion**

On behalf of the Tennessee Pharmacists Association, pharmacists in Tennessee applaud your efforts to ensure that patients, including those in our home state of Tennessee, have affordable access to safe, effective, and high-quality prescription drug therapies. Thanks again for the opportunity to submit comments for your consideration, and please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Micah Cost', is positioned above the printed name.

**Micah Cost, PharmD, MS**  
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