

December 31, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4185-P
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov
Re: CMS-4185-P

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the proposed changes to the Medicare Advantage, Medicare Fee-for-Service, and the Medicare Prescription Drug Benefit programs (CMS-4185-P). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals each year.

The following comments are informed by our experience assisting beneficiaries, their family members, and health care professionals as they navigate selecting and accessing care through a Medicare Advantage (MA) or Part D plan. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Casey Schwarz, Senior Counsel, Education & Federal Policy at CSchwarz@medicarerights.org or 212-204-6271.

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits

In addition to implementing the specific requirements of the Bipartisan Budget Act of 2018 (BBA) which allow MA plans to treat certain additional telehealth benefits as Original Medicare benefits for the purpose of bid submission and payment, the Centers for Medicare & Medicaid Services (CMS) also proposes to continue and expand the telehealth benefits that plans may offer as supplemental benefits—for example, coverage for telehealth services that do not meet the requirement of being covered under Part B when they are provided in person.

We support CMS's proposed requirement preserving patient choice—that a plan is required to make both telehealth and in-person access available for all services it would cover as an additional telehealth benefit. Moreover, CMS should monitor the differential co-insurance amounts for telehealth versus face-to-face to ensure that they fairly reflect actual cost differentials and are not used to steer beneficiaries away from their preferred methods of care.

We support the broadening of telehealth options for supplemental benefits, such as supplemental dental benefits. Expanded telehealth for oral health care could increase access to care in underserved areas and connect beneficiaries to diagnostic and preventive services earlier, as well as help beneficiaries receive services where they are, including in nursing facilities and senior centers, instead of having to travel to a dental office.

CMS should work, to the extent possible under federal law, to ensure parity for Original Medicare. Broadening the basic benefit coverage, though a positive for Medicare Advantage enrollees, comparatively disadvantages beneficiaries receiving Medicare through fee-for-service.

CMS should clarify that a Qualified Medicare Beneficiary (QMB) would be protected from billing for co-pays and deductibles for all Part A and Part B services delivered by telehealth, including those that would not be covered in fee-for-service because of statutory restrictions. Without this protection, a QMB would face the anomalous situation of payment protection for an inpatient visit and charges for telehealth. This would be particularly unfair because CMS is proposing to allow differential co-insurance rates for telehealth and in-patient for plan members who are not QMBs.

CMS should also require plans to demonstrate how they intend to address inequalities in access to the internet and devices so that telehealth benefits are available to all their members.

2. Dual Eligible Special Needs Plans

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.11, and 422.752)

Overall, we support greater integration in Dual Eligible Special Needs Plans (D-SNPs) and agree that there has been a longstanding need to address the fragmentation of information that dual-eligible beneficiaries face when trying to access care. New, heightened requirements for integration are essential and we applaud CMS for putting forth new minimum requirements; however, we encourage CMS to go further. As noted in more detail below, we recommend increased specificity in requirements and strong oversight to ensure that integration requirements are being met and that dual-eligible beneficiaries enrolled in D-SNPs are actually benefiting from increased integration.

(1) Definitions of a “Dual Eligible Special Needs plan”, “Fully Integrated Dual Eligible Special Needs Plan”, “Highly Integrated Dual Eligible Special Needs Plan”, and “Aligned Enrollment” (§ 422.2)

We appreciate CMS’s effort to standardize and define various types of plans. We are concerned, however, that the inclusion of “Highly Integrated Special Needs Plan” may cause confusion in the market place about what is particularly special or distinct about these special needs plans. It is already difficult for consumers and advocates to determine which plans are D-SNPs and what type of D-SNP they are. This is especially true where, as CMS notes, “[the agency] interpret[s] the statutory language on assuming clinical and financial responsibility for benefits (as [required under section 1859 (f)(8)(D)(i)(III) of the Act and] discussed later in this proposed rule) to mean that such a D-SNP would always satisfy the requirement of being a FIDE SNP or HIDE SNP.¹” This confusion about what it means, from a beneficiary’s perspective, to be is also highlighted in CMS’s discussion of its proposed definition of “aligned enrollment,” discussed below. Clear, consistent regulatory definitions can begin to make the

¹ Proposed Rule at 54993.

important differences and distinctions between these plan types (and beneficiary options) more understandable. Accordingly, we urge CMS to incorporate these definitions and markers into beneficiary-centered materials, including the Plan Finder tool. In addition, plan documents, including ID cards, should be required to include the D-SNP, FIDE SNP, or HIDE SNP designation.

We applaud CMS's recognition of the need to interpret the meaning of the statutory language "arranging for benefits." We agree with the proposed interpretation to mean to "coordinate the delivery of Medicare and Medicaid benefits"; however, we believe that CMS should be more prescriptive in identifying which plan activities constitute coordination in the proposed D-SNP definition. In our experience, D-SNPs provide little to no coordination; instead, they offer what is closer to CMS's explanation of what is not coordination: "telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program (that is, the state agency or Medicaid managed care plan versus the D-SNP), and offering additional support if needed."² As a result, plan members are often confused about their coverage, have difficulty accessing services, and do not receive the care they need and to which they are entitled. While CMS has addressed this issue in the comments to the proposed rule,³ we urge CMS to go further and embed in the final rule specific, illustrative but not exhaustive examples of plan actions that meet its definition of coordination.

CMS should include in its final definition of a D-SNP different and specific types of coordination activities. For example, language that D-SNPs should:

- Staff their plans with care coordinators who are trained in Medicare, Medicaid, and plan benefits, have passed skills tests, and have limited caseloads.
- Provide comprehensive information about Medicare, Medicaid, and plan benefits through plan materials, customer service, and care coordinators.
- Ensure not only that members have a primary care physician, but also that their providers are actively communicating through models such as Interdisciplinary Teams.
- Share information about claims, service authorizations, and care plans with the state, providers, beneficiaries, and beneficiaries' appointed representatives
- Provide assistance with filing grievances and appeals, as well as comprehensive explanations of the appeals process.

(2) Dual Eligible Special Needs Plans and Contracts with States (§ 422.107)

We support the imposition of a notification requirement in contracts between state Medicaid agencies and plans regarding patient care, as required by the Act, but do not believe the notification proposal in § 422.107 is sufficient. In our experience with New York's duals demonstration (FIDA), where one plan has data on all of a patient's needs and current health status, some individuals are still discharged from inpatient facilities without adequate care plans in place. At other times, members are left in a facility awaiting an assessment and the provision of HCBS that would allow them to go back into the community. The dangers of insufficient coordination and communication are further increased in the case of D-SNPs

² Proposed Rule at 54994.

³ *Id.*

that are not FIDE SNPs or HIDE SNPs, where a vulnerable patient is switching between services covered by their D-SNP and those covered by FFS Medicaid or a different Medicaid Advantage Plan.

With that in mind, we believe CMS should require D-SNPs to notify the state for all plan members being discharged from inpatient care, rather than a sub-group. Although some D-SNP members may only be partial-duals, the transition from an inpatient facility to the community is often a challenge, and therefore the appropriate time for a care coordinator to engage them in a conversation about full Medicaid eligibility or assist them with access to home health benefits and any necessary therapies. We appreciate the desire to allow state Medicaid agencies some latitude in creating procedures and protocols for meeting this notification requirement; however, we think it is necessary for CMS to impose a timeframe for the notification to occur. We recommend that notification should be required within 48 hours of admission to a hospital or skilled nursing facility in order for the D-SNP and Medicaid payor to monitor the beneficiary's condition as a means to timely plan, prepare, and assist at the time of discharge and transition to a new care setting. We further believe that D-SNPs must do more than simply send information, they should be required to take steps to ensure that each member is able to access needed Medicaid services including those, such as HCBS, that would allow them to receive care in the least restrictive environment. This is especially important in the 20 states in which duals access their Medicaid services under FFS exclusively. Again, simply sending data in these situations is not enough to provide adequate coordination; instead, CMS should include detailed protocols for communication and coordination such as is found in California's guidance for MMPs on hospital discharge planning.⁴ CMS should also look to models like Interdisciplinary Teams for ways to better create person-centered decision making that will protect patients during vulnerable times such as transitions between care settings.

We agree that awareness, understanding, and training of plan staff and providers about the availability of LTSS, Home and Community Based Services (HCBS), and behavioral services covered by Medicaid is an intrinsic administrative function of a D-SNP. We think it necessary that CMS explicitly state this point in the final rule to ensure that all plans also understand this. This could be done, for instance, by including a new sub-part at §422.107(c)(1)(i):

The responsibility to provide and coordinate the delivery of Medicaid benefits includes, but is not limited to, training plan staff and network providers on all of the services covered by both Medicare and Medicaid.

We agree that it is important that D-SNPs with exclusively aligned enrollment solicit state input on the plan's model of care, health risk assessment instrument, and beneficiary communication materials. Rather than informing states that they may choose to add this to their contract with D-SNPs, we encourage CMS to make this requirement the default. States should be providing this input and, thereby, staying active in their role as a regulator of plans operating within their boundaries. Rather than having states opt-in to their regulatory role, we urge CMS to put in place and carefully oversee an opt-out process, through which states can assert that it is unnecessary for them to respond to D-SNP solicitations for input. This is appropriate even in states without D-SNPs with exclusively aligned enrollment, since the state should still have an interest in ensuring beneficiary materials have correct state-specific information. For example, such a state should be ensuring that beneficiary materials going out from D-SNPs have information about Medicare Savings Programs or Medicaid eligibility and enrollment rules specific to that state.

⁴ Discharge Planning for Cal MediConnect (DPL 16-003) (July 2016)
<https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPsandPolicyLetters/DPL2016/DPL16-003.pdf>

We disagree with CMS's decision not to require that D-SNPs share data with state Medicaid agencies or entities designated by State Medicaid Agencies. Instead, CMS should create a shared data system for use by states, plans, providers, and beneficiaries to access health records, claims, service authorizations, and care plans. Ombudsman programs and community-based organizations working with participants, when granted individualized permission, should also be able to access the shared data system.

The creation and use of a shared data system that allows authorized users to access health plan records would improve communication between providers, health plans, and participants. For example, if a provider were able to know what other tests and services were previously ordered, they could seek out those results, rather than duplicating efforts and expenses. It could also lessen beneficiaries' confusion about their coverage or plan of care. Allowing for access to integrated data could strengthen and improve the care planning and service authorization process, in part by reducing the amount of phone time and number of phone calls that providers, care managers, advocates, caregivers, and beneficiaries often experience when trying to access information from a health plan or provider. While any such shared system requires significant resources to set up, this is greatly outweighed by the long-term and even short-term savings of increased efficiency, improved quality of care, and reduction of administrative burden on all parties.

We support the revision to the requirement that contracts between D-SNPs and the state Medicaid agency should not only document the categories of dual-eligible individuals who are eligible to enroll but should also include any additional criteria of eligibility. This information must also be made publicly available so beneficiaries and those assisting them have a clear understanding of the eligibility requirements. We have worked with beneficiaries who have experienced confusion and frustration in not understanding why they are unable to enroll in a particular D-SNP and, specifically, instances of D-SNPs that do not clearly identify whether they accept partial dual eligibles.

It is important that Medicaid services provided by a D-SNP be clearly identified so beneficiaries are aware of the services they should be able to access and receive through their D-SNP. Therefore, we support CMS's proposal that the contract between the D-SNP and the state Medicaid agency must include the Medicaid-covered services that the D-SNP is responsible for covering. We recommend that the contract include a list of all Medicaid covered services and then identify which of those services will be covered by the D-SNP. This would allow for better plan comparison as it would present the full array of Medicaid benefits and then note exactly which benefits the D-SNP is covering.

We also encourage CMS to further explore utilizing the Contract Management Team (CMT) approach used in the dual-eligible demonstrations with D-SNPs. Without a unified approach to oversight, plans may be able to operate between the State Medicaid office and CMS, playing one regulator against the other, with neither fully understanding the situation nor taking necessary action when issues arise. In the financial alignment demonstrations, the CMT has been considered invaluable by all players. The CMT can resolve issues as they arise, monitor plan compliance with their contracts, respond to beneficiary complaints, coordinate with ombudsman offices, and review grievances and appeals. The CMT also proved valuable in resolving any differences in Medicare and Medicaid policies during implementation.

(4) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans

We share CMS's concern about whether D-SNPs offer value to partial-benefit dual-eligible individuals (partial duals). We encourage CMS not to permit blanket enrollment of partial duals in D-SNPs and instead consider either entirely prohibiting or limiting partial-dual enrollment. One possible limitation

would be to permit only QMB-Only partial duals, but not SLMB-Only or QI enrollees. In any situation where the agency does permit partial dual enrollment, the D-SNP should be required to set out specifically how it will meet the needs of its partial-dual members in a way that is distinct from the benefits that a non-D-SNP Medicare Advantage plan would offer.

Because the core mission of D-SNPs is coordination of Medicare and Medicaid benefits, we also ask that CMS place marketing restrictions on D-SNPs so they cannot primarily target partial duals who may have lower acuity and less significant health care needs than full duals, and that CMS carefully monitor enrollment patterns.

(5) Suspension of Enrollment for Non-Compliance With D-SNP Integration Standards (§ 422.752)

We support suspension of enrollment in a D-SNP that is not in compliance with the integration standards. Oversight is crucial and we encourage mechanisms to ensure that D-SNPs are operating in accordance with the integration requirements. The proposal allows for suspension of enrollment during 2021 through 2025. We request that CMS evaluate this sanction in order to make recommendations for beyond 2025.

b. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560-562, 422.566, 422.629-634, 438.210, 438.400, and 438.402)

We agree that it is necessary to create unified grievance and appeals procedures for D-SNPs and Medicaid Managed Care plans in order to for dual eligible beneficiaries to have a simpler process that is easier to access and navigate. We recognize the complexities involved in aligning the Medicare and Medicaid grievance and appeals processes and applaud CMS for taking these first steps. In New York, the FIDA program has allowed beneficiaries, caregivers, providers, plans, and advocates to experience the benefits of a fully integrated grievance and appeals process. We strongly urge that the unified grievance and appeals process be extended beyond the plan level and include the Medicare Part D appeals process.

We support CMS's effort to develop and implement a unified grievance and appeals process.

(1) Assisting with Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

We strongly support the proposal to require D-SNPs to assist beneficiaries with access to Medicaid benefits, appeals, and grievances regardless of whether the beneficiary's request for services, appeal, or grievance is related to Medicaid fee-for-service or a Medicaid Managed Care plan. In our experience working with beneficiaries, it is too often that we encounter D-SNP enrollees who have been turned away by their plan or simply directed to the Medicaid helpline when they have questions about trying to access Medicaid services. Staff at various D-SNPs have often told our clients that their plan is only concerned with Medicare coverage and to access Medicaid benefits they must contact entirely separate organizations. Often, the D-SNP does not even have the ability to direct enrollees to a specific office or phone number, and sometimes they have even given the incorrect agency name.

We agree that it is appropriate to require D-SNPs to assist with completing forms and obtaining documentation to support a request for authorization or appeal. This should apply to all D-SNPs even those without aligned enrollment. The D-SNP should be required to assist the beneficiary or their appointed representative unless assistance is declined. The care coordinators providing this assistance must be adequately trained and competently skilled in coaching a beneficiary or their appointed representative in how to self-advocate and how to navigate the relevant appeals process. The care

coordinators and plan staff tasked with this responsibility must have a concrete understanding of their role and know that their primary charge is to best assist the beneficiary. Plan staff must be empowered to act in the best interests of the beneficiary they are assisting and not have concern that the plan expects the staff to act in the interest of the plan, for example, by discouraging a person from seeking an appeal.

We also agree that data sharing is essential to allow D-SNPs to access information about their enrollees' Medicaid enrollment status and benefits in order to be fully informed about enrollees coverage and needs. By holding itself out as a plan that specifically serves dual eligibles, D-SNPs present themselves as providing better coordinated care; therefore, plans must have processes in place to access this necessary information for the purposes of fulfilling the promise and requirement of care coordination and integration.

(3) Definitions of “Applicable Integrated Plan”, “Integrated Appeal”, “Integrated Grievance”, “Integrated Organization Determination”, and “Integrated Reconsideration”, and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629)

We recognize that creating an integrated grievance and appeals process is more manageable in the context of exclusively aligned enrollment. Since CMS proposes that the integrated process apply only to applicable integrated plans such as FIDE and HIDE SNPs at this time, we recommend that CMS actively learn from this experience to better explore expanding the integrated appeals process in the future—so that all full dual-eligible individuals can experience a less confusing and complicated appeals and grievance process. We encourage CMS to continually seek opportunities to make the dual eligible experience “no wrong door.”

It is not enough for CMS to simply require applicable integrated plans to create integrated processes to administer uniform grievance and appeals requirements. CMS must provide a detailed framework for the required processes in order for there to be uniformity and transparency amongst the applicable integrated plans. We appreciate that CMS wishes to allow for some plan flexibility and innovation, but it is essential that CMS give plans a clearer understanding of how to proceed as well as minimum standards for integration and beneficiary access. CMS must also give beneficiaries and their advocates a set of expectations to which plans will be held. We therefore strongly urge CMS to develop more detailed guidance and expectations for the administration of the integrated processes.

In the proposed rule, CMS notes that states may go further and confirms that they have flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries. We appreciate this clarification.

(4) Authorization for Filing Appeals (§ 422.629(l))

It is important to remove any barriers to beneficiaries' ability to file appeals. In New York, we have seen delays in filing Medicaid appeals due to a state or local insistence on obtaining the written authorization of a representative to act on an individual's behalf. Therefore, we support incorporating the Medicare Advantage regulations at § 422.566 (c) that allow a provider to file an appeal on behalf of a beneficiary without written authorization, but require the provider to provide notice to the beneficiary in most circumstances. However, we agree with CMS's proposal that beneficiaries who may face recoupment as a result of aid-continuing as part of an appeal must provide written consent where the provider is making the request.

(5) Integrated Grievances (§ 422.630)

We agree that beneficiaries should be able to file a grievance at any time and that the integrated grievance process should adopt the Medicaid regulation at § 438.402 (c)(2)(i) rather than the MA regulation (§ 422.564 (d)(a)) that limits filing a grievance to within 60 days of the event at issue. We also support the decision to preserve beneficiaries' continued option, to the extent it exists, to file a grievance directly with the state. However, it is important that the D-SNP and the state are transparent about the beneficiaries' choices as to where to file the grievance. There should also be a no wrong door policy. For example, if a submitted grievance needs to be redirected to a more appropriate entity, the receiving entity should assist with this process and keep the beneficiary informed.

(6) Integrated Organization Determinations (§ 422.631)

We support CMS's proposal to specify content requirements for the integrated determination notices which are required to be written in plain language and available in the language and format that is accessible to the beneficiary. We suggest that CMS develop model notices and language to guide plan development and that there be sufficient oversight to ensure that beneficiaries are in-fact receiving notices in the language and format most accessible and appropriate for them. We often hear from beneficiaries who have received notices that are not in their primary language or in the most accessible format, despite repeatedly informing their plan about their needs.

We support the proposed timelines for sending notices and issuing decisions.

(7) Continuation of Benefits Pending Appeal (§ 422.632)

We support the continuation of Medicare benefits under Part A and Part B and Medicaid benefits while an appeal is pending. However, while the integrated appeals process is currently only proposed through the plan-level appeal, we recommend that the continuation of benefits proceed throughout the additional levels of appeals. Beneficiaries have the opportunity to request the continuation of benefits when proceeding to a state-administered fair hearing; however, this is not an option for Medicare benefits under Part A and Part B to the level of impartial review. Offering continuation of benefits pending appeal is necessary to minimize disruptions in needed care. Doing so in this limited way, however, undercuts these goals and significantly diminishes the protections for beneficiaries. It is especially troubling to terminate continuation of benefits pending appeal prior to any independent review of the case, as the first level of review is internal to the plan that made the initial determination.

CMS also notes that since there are relatively few Medicare benefits that are continuing in nature, no significant financial cost is anticipated to implement this provision.

We also recommend that the continuation of benefits remain in place through subsequent levels of appeals without the need for the beneficiary to make additional requests. Under the FIDA program, the preservation of aid continuing through all levels of appeals without the burden of repeated requests at each level has been extremely helpful to beneficiaries and has reduced the stress and fear attendant to denials of critically needed care.

We fully agree with and applaud the proposal that beneficiaries have no financial liability for the cost of services provided pending appeal. We agree with the prohibition of financial recovery by the managed care plan, Medicare, and Medicaid for the benefits provided during the appeal. It is not uncommon that we assist a Medicaid beneficiary who is hesitant or declines aid continuing in fear of the possible financial liability. This results in the individual going without much needed services for a period of time, and the possibility of more significant needs or worsened conditions when services are resumed after a

favorable decision. The threat of financial recoupment for continuation of benefits seems contrary to the goals of this proposed rule and we are pleased to see this provision that would protect low-income individuals from this risk.

(8) Integrated Reconsiderations (§ 422.633)

We agree that beneficiaries and their representatives should have the right to review their medical records in the case file, consistent with the protection for Medicaid enrollees under § 438.496 (b)(5). However, we recommend that CMS establish a timeframe within which the plan must send the case file to the beneficiary or their representative. In New York, we have seen varied practices amongst Medicaid plans in terms of when they send out the case file or if they comply with this requirement at all. We urge CMS to require that the case file be automatically mailed to the beneficiary or their representative once the request for the appeal is received, and that in any event the beneficiary or their representative receive the case file within 10 days of the plan's receipt of the request for the appeal. Plans should not be permitted to charge beneficiaries or their representatives for the provision of the case file.

We support the proposal that plans accept an oral request for a reconsideration as sufficient to initiate a reconsideration and that the beneficiary should not be required to follow up the oral request in writing. We agree that such a requirement would create an additional burden for beneficiaries.

We agree that the required decision timeframe for resolving pre-service and post-service appeals should be the same since the goal of a uniformed appeals process is to simplify the process and make it easier for beneficiaries to navigate. We support the proposal that all standard integrated reconsiderations be resolved within 30 calendar days. Additionally, we agree that plans should be required to send a written determination notice in all circumstances. We agree with the proposed required content of the determination notice—that it include an explanation of the next level of appeal and what steps the enrollee must take to further pursue the appeal—and recommend that the notice also include information about how to get assistance with the next level of appeal.

(10) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

We encourage CMS to consider ways to implement a fully integrated appeals process through all levels of appeals. The New York FIDA demonstration has proven that it is possible to create such a process and it works well for all parties involved. The concerns—raised in this proposed rule and also at the advent of the FIDA program—that a specialized unit of administrative law judges may not be able to adjudicate both Medicare and Medicaid law proved not to be an issue. The auto-forwarding of the appeals and the aid continuing has worked in the best interest of the FIDA beneficiaries. There has been much greater ease accessing and navigating the appeals process for beneficiaries, their representatives, caregivers, providers, plans, and advocates.

We applaud CMS for further exploring how to integrate grievances and appeals beyond the plan level and recommend that this further exploration also include Medicare Part D prescription drug appeals. The current Part D process is weighed down by excessive paperwork and administrative error, and severely lacks transparency. Beneficiaries, their prescribers, and their pharmacists are often unaware of how to challenge a plan's decision. As a result, many beneficiaries miss the formal appeals process entirely. Instead, they either leave the pharmacy empty-handed, accepting the resulting consequences of their health, or they pay the full cost of the drug out of pocket, if they can afford to do so.

For beneficiaries who do request a coverage determination, it is only after this coverage determination is made that the beneficiary has any appeal rights. However, rather than appealing to an independent entity, the beneficiary once again must make an appeal to the plan. The current Part D appeals process allows the plan to have three opportunities to make a decision about coverage: the decision at the pharmacy counter, the coverage determination, and the coverage redetermination. From our experiences, this process confuses beneficiaries, prescribers, and pharmacists and often deters beneficiaries from pursuing an appeal.

The Part D appeals process is riddled with deficiencies. As CMS considers an integrated process for dually eligible beneficiaries, and in particular at this time when great strides are occurring in improving care and the health coverage experience for the dual eligible population, it would be a disservice to not evaluate ways to also improve and integrate the Part D appeals process.

3. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

The Bipartisan Budget Act of 2018 provides that the Secretary shall establish a process by which Prescription Drug Plans (PDPs) may request current claims data for its enrollees. The purposes for which plans may and may not use such data are circumscribed by law and under the proposed rules. The Act specifically allows for data to be used for “(i) Optimizing therapeutic outcomes through improved Medication use; (ii) improving care coordination to as to prevent adverse healthcare outcomes. . .” and may not be used “(i) To inform coverage determinations under Part D; (ii) to conduct retroactive reviews of medically accepted conditions; (iii) to facilitate enrollment changes to a different PDP or a MA–PD plan offered by the same parent organization;[or] (iv) to inform marketing of benefits.” The Act also gives the Secretary discretion to expand upon these approved and unapproved uses. CMS proposes to do so by expanding the permissible uses to include “fraud and abuse detection and compliance activities”; to facilitate “health care operations” under 45 CFR 164.501; or to disclose the information “as required by law.”⁵

We are concerned that these expanded uses conflict, or have the potential to conflict with the directive in the statute that PDPs may not use this information “to inform coverage determinations under Part D” or to conduct retroactive reviews of medically accepted indications.” In particular, we are concerned about its use for “fraud and abuse and compliance activities,” which include identifying and reconciling payments and coverage for arguably non-covered drugs—including those which may have been prescribed for an off-label use. We encourage CMS to test this disclosure, and the attendant risks, with only those uses expressly allowed by statute, and to consider expansion only once the Secretary has evaluated plans’ actual use of this data as well as the agency’s audit and review capacity.

We are also concerned that the attestation of the PDP that it will use the data for only the approved purposes and not for the expressly forbidden purposes is insufficient as it stands. We encourage CMS to create and administer training materials that include specific examples of appropriate and inappropriate usage, to establish a procedure to regularly oversee the actual use, and to closely monitor the coverage denial, marketing, and enrollment activities of any PDPs that request such data to look for patterns that might reflect improper usage of this data.

B. Improving Program Quality and Accessibility

⁵ Proposed rule at 55106

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

d. Updating Measures (§§ 422.164, 423.184)

(1) Proposed Measure Updates

(b) MPF Accuracy

We support the changes to include both the magnitude and frequency of price discrepancies on the Medicare Plan Finder, and to expand the days' supply of claim included. Beneficiaries rely on the accuracy of the plan finder tool to make critical coverage decisions.

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs ((§§ 423.568, 423.570, and 423.572)

CMS proposes a clarification to the timeframe required for a response to an exception request where a prescribing physician or other prescriber's supporting statement has not been received by the plan by limiting the amount of time a plan can hold a request pending that statement. Currently, the plan is required to respond to a request for an exception or a coverage determination as quickly as the enrollees' health requires, but no later than 72 hours after the request or, for an exception request, the prescriber's supporting statement. Current guidance also requires plans to make a determination based on whatever evidence exists if a supporting statement is not received within a "reasonable period of time."⁶

Here, CMS, in effect, defines that "reasonable period of time" as 11 days by establishing that a plan must issue its decision no later than 72 hours after the receipt of the prescriber's supporting statement or 14 calendar days after the receipt of the request, whichever occurs first.

While we support CMS's intention and the additional clarity that this rule provides, we encourage CMS to choose a shorter time period. The timeframe for adjudication for prescription claims is short because delays in access to needed medicines can have serious effects. Though we appreciate that the previous "reasonableness" standard left room for interpretation and may have even resulted in longer wait times, the imposition of the more explicit deadline should err on the side of a timely response.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA Cost Plans and PACE

(4) Claim Denials and Beneficiary Notification

We strongly support the extension of a time period for beneficiary notification for any providers newly added to the preclusion list, and of a 60 day period of time post-beneficiary notice before the plan denies any claims from that excluded provider.

(5) Beneficiary Appeals

We urge CMS to permit limited beneficiary appeals of denials of claims based upon a provider or prescriber's inclusion on the preclusion list. If the beneficiary notice described previously was incomplete

⁶ *Id.* at 55028.

or ineffective, the beneficiary should not be responsible for payment. CMS should consider mechanisms that would protect beneficiaries from liability to the provider in such circumstances.

(7) Beneficiary Liability

We appreciate and support this limitation on beneficiary liability, but encourage CMS to expand such protection to non-contracted entities in two circumstances: first, where the provider was a contracted individual or entity prior to their preclusion but whose contract was terminated as a result of the preclusion; and second, where the MA is a PPO and offers out-of-network coverage.

2. Medicare Advantage Risk Adjustment Data Validation Provisions (§§ 422.300, 422.310(e), and 422.311(a))

We support CMS's proposal to recover overpayments to MA plans based on extrapolated audit findings through the use of random-sampling techniques. As noted by CMS, such action is necessary to ensure plans and providers are paid appropriately, to protect the integrity of the Medicare program, and to serve the public interest by recouping public money improperly paid to private insurers.⁷ We also agree with CMS that such action should be taken retroactively in the interests of protecting the Medicare program and because plans were previously put on notice that CMS would be using such a system to find and correct overpayments. While we do not take a stance on CMS's preferred methodology, we strongly support its efforts to establish an efficient and effective system for ensuring that MA plans are appropriately paid and improperly paid funds are identified, calculated, and refunded to the Medicare trust fund.

⁷ Proposed Rule at 55037-55041.