ONLINE APPENDIXES 14

The Medicare prescription drug program (Part D): Status report

ONLINE APPENDIX 14-A

How Part D's coverage-gap discount affects financial incentives to use biosimilars

We illustrate the incentives facing plan sponsors and beneficiaries using a hypothetical example that compares an originator biologic that costs $30,000 with a biosimilar that costs 15 percent less, or $25,500 (Table 14A-1). (This hypothetical example does not take into account any changes in "current law" made subsequent to the passage of the Bipartisan Budget Act of 2018.) In this example, we assume that the plan has negotiated a rebate of 20 percent for both products, or a rebate of $6,000 and $5,100 for the originator biologic and the biosimilar, respectively. We estimate the financial effects of using Part D's defined standard benefit for 2018, but with the coverage gap fully phased out (as it will be in 2020).[1]

Case 1 shows the situation of the biosimilar under current law. Superficially, it would appear that, between the originator biologic and its biosimilar, the plan sponsor would find it more desirable to put the biosimilar on its formulary because the biosimilar's net-of-rebate price ($20,400) is lower than the originator biologic's net price ($24,000).

However, the plan sponsor must also consider other sources of payment for the drug. Under Part D's benefit structure, an enrollee would pay $3,556 in cost sharing for the originator biologic compared with $5,336 for the biosimilar. Beneficiary cost sharing would be lower for the originator biologic because it qualifies for a coverage-gap discount of $2,506, while the biosimilar does not. Moreover, under current law, the coverage-gap discount is counted toward Part D's out-of-pocket (OOP) spending threshold.

Of the originator product's remaining gross price, Medicare's reinsurance would pay for the vast majority of spending in the catastrophic phase ($16,991), and the plan's liability would be $6,947. By comparison, the plan's share of gross spending would be much higher for the biosimilar at $14,792 because of the interaction between the coverage-gap discount and rebate provisions. If there were no coverage-gap discount, the enrollee would pay 25 percent cost sharing and the plan would cover 75 percent for a longer period of benefit spending until the enrollee reached the OOP threshold. The enrollee would pay 5 percent cost sharing thereafter. By counting $2,506 in coverage-gap discounts toward the OOP threshold, an enrollee taking the originator biologic would reach the OOP threshold at a lower level of gross drug spending ($8,762) than if the enrollee took the biosimilar ($18,785).

In the same way that cost sharing reduces a plan's liability for drug spending, so do manufacturer rebates. Under current CMS guidance, Medicare keeps a portion of rebates to offset the costs of reinsurance that the program pays to plans. In the case of the originator biologic, Medicare would retain $1,564 of the $6,000 rebate for the originator biologic, and the plan would keep $4,436. By comparison, the plan would keep $3,770 of the $5,100 rebate for the biosimilar.[2]

Under current law, after netting out all other sources of payment, the plan sponsor would have a strong financial incentive to put the originator biologic on its formulary rather than the biosimilar. In Case 1, the plan's net liability for the originator biologic would be less than a fourth of that for the biosimilar under current law ($2,512 compared with $11,022). Because the manufacturer discount is credited as if it were the enrollee's own OOP spending, patients who take the originator biologic would reach the OOP threshold more quickly than if they took the biosimilar. As a result, more of the originator biologic's cost is paid by Medicare's individual reinsurance. In this example, Medicare's individual reinsurance payment is $15,426 for the originator biologic compared with $4,042 for the biosimilar.

Column 1 of the lower tranche of Table 14-A1 (p. 4) shows the effects of excluding the coverage-gap discount for the originator biologic from counting toward the OOP threshold. Under this scenario, the beneficiary would pay more in cost sharing, $5,561 versus $3,556. At the same time, the manufacturer of the originator biologic would also pay a larger discount, $7,518 versus $2,506, because the coverage-gap discount would continue to apply until the point at which the beneficiary reached the OOP threshold entirely with her own cost sharing—at $18,785 in gross drug spending. Only at that higher level of spending would Medicare become responsible for reinsurance payments. After considering all payments for the originator biologic including rebates, the plan would receive $7,408 in net Medicare reinsurance and net plan liability would be $3,514.

The scenario described in Case 1 (in the upper tranche of Table 14-A1) illustrates the concern that, under current law, the structure of the Part D benefit and Medicare's reinsurance payments give plan sponsors financial incentives to place higher priced products on their formularies rather than lower priced ones. It remains to be seen whether biosimilars will have lower prices than their originator products as they enter the market. If they

TABLE 14–A1

Hypothetical illustration of how Part D's coverage-gap discount affects financial incentives to use biosimilars

Spending for a beneficiary who takes one biologic product			Originator biologic with 20% rebate	Biosimilar with 20% rebate: Case 1: No gap discount (current law)	Biosimilar with 20% rebate: Case 2: With gap discount
Annual cost measured at gross and net prices					
Gross (list) price			$30,000	$25,500	$25,500
Rebate		**A**	$6,000	$5,100	$5,100
Net of rebate price		**B**	$24,000	$20,400	$20,400
Gross drug spending					
Beneficiary cost sharing		**C**	$3,556	$5,336	$3,331
Coverage-gap discount		**D**	$2,506	$0	$2,506
Covered benefits	Medicare reinsurance	**E**	$16,991	$5,372	$13,391
	Plan liability	**F**	$6,947	$14,792	$6,272
Subtotal			$30,000	$25,500	$25,500
Rebate allocation (based on gross spending)*					
Medicare **(A x (1/3) x 0.8)**		**G**	$1,564	$1,330	$1,330
Plan **(A – G)**		**H**	$4,436	$3,770	$3,770
Net effect					
Beneficiary cost sharing **(C)**			$3,556	$5,336	$3,331
Medicare reinsurance after rebates **(E – G)**			$15,426	$4,042	$12,061
Plan liability after rebate and reinsurance **(F – H)**			$2,512	$11,022	$2,502
Gross spending at OOP threshold			$8,762	$18,785	$8,762
		Exclude coverage-gap discount from OOP threshold			
Gross drug spending				**Same as above**	
Beneficiary cost sharing		**I**	$5,561		$5,336
Coverage-gap discount		**J**	$7,518		$7,518
Covered benefits	Medicare reinsurance	**K**	$8,972		$5,372
	Plan liability	**L**	$7,950		$7,275
Subtotal			$30,000		$25,500
Net effect				**Same as above**	
Beneficiary cost sharing **(I)**			$5,561		$5,336
Medicare reinsurance after rebates **(K – G)**			$7,408		$4,042
Plan liability after rebate and reinsurance **(L – H)**			$3,514		$3,505
Gross spending at OOP threshold			$18,785		$18,785

Note: OOP (out-of-pocket). This example estimates financial effects using Part D's defined standard benefit for 2018, but with the coverage gap fully phased out (as it would be in 2020).
*We assume one-third of the plan's gross covered spending is above the OOP threshold. Medicare's share of the rebate is calculated as the reinsurance rate (80 percent) multiplied by the rebate amount multiplied by the percentage of gross spending above the OOP threshold. In 2015, the gross (list) cost of Humira (including Humira pen) averaged $29,278 per user per year (CMS's 2015 Medicare drug spending data (https://www.cms.gov/Research-Statistics-data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015MedicareData.html.))

Source: MedPAC analysis.

do, and if plan sponsors are not motivated to encourage their use, enrollee premiums and program spending will be higher, as will overall drug spending.

In Case 2, we lay out a situation in which the coverage-gap discount applies to both the originator biologic and its biosimilar. The beneficiary would pay less cost sharing ($3,331) because now the manufacturer would pay a coverage-gap discount of $2,506. Initially, we assume that, as under current law, the coverage-gap discount would be counted toward Part D's OOP threshold. For this reason, the beneficiary would reach the OOP threshold at a lower level of gross drug spending ($8,762) than in Case 1 ($18,785). The plan's liability net of all other sources of payment would be lower for the biosimilar ($2,502) than for the originator biologic ($2,512). The biosimilar would also be the lower cost option for the beneficiary ($3,331 compared with $3,556 for the originator biologic) and for Medicare ($12,061 compared with $15,426 for the originator biologic).

However, in isolation, the policy change in Case 2 could worsen the financial situation for the Medicare program by further accelerating growth in reinsurance spending because the beneficiary would reach her OOP threshold at a lower level of gross drug spending ($8,762 compared with $18,785 under Case 1). Medicare would pay about three times the amount of reinsurance in Case 2 ($12,061) than in Case 1 ($4,042).

The scenario in which the biosimilar's coverage-gap discount no longer counts toward the OOP threshold is depicted in the lower tranche of Table 14-A1 for Case 2. Because treatment of the discount on both the originator biologic and the biosimilar would be equalized in this respect, the beneficiary would reach that threshold at the higher amount of gross drug spending ($18,785). Beneficiaries would pay less cost sharing for the biosimilar ($5,336) than for the originator biologic ($5,561). Likewise, the plan's net liability would be lower for the biosimilar ($3,505) than for the originator biologic ($3,514). ■

Endnotes

1 Using the 2018 benefit structure (with the partial phase-out of the coverage gap) somewhat reduces the magnitude of the financial effects but does not materially change the resulting plan incentives.

2 We assume one-third of the plan's gross covered spending is above the OOP threshold. Medicare's share of the rebate is calculated as the reinsurance rate (80 percent) multiplied by the rebate amount multiplied by the percentage of gross spending above the OOP threshold.

ONLINE APPENDIX 14-B

Part D exceptions and appeals

In its June 2016 report to the Congress, the Commission recommended changes to Part D, including giving plan sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees (Medicare Payment Advisory Commission 2016). Because plans would have greater flexibility to use management tools, the Commission also noted that CMS would need to ensure that Part D exceptions and appeals processes function effectively. To help monitor those processes, this appendix provides information about Part D coverage determinations, exceptions, and appeals.

Background

The vast majority of enrollees are satisfied with their Part D plans: One recent survey found that 86 percent believe their plan works well and without hassle (Healthcare Leadership Council 2017). Nevertheless, a small share of enrollees has more difficulty acquiring their needed medication, which can occur for a number of reasons, such as:

- the physician writes a prescription for a drug not covered by Part D,
- the drug is not on the plan's formulary,
- the patient has reached a quantity limit on the drug or must try a "fail-first" medicine before receiving the prescribed drug, or
- the pharmacy needs additional information before it can dispense the drug because of prior-authorization requirements.

Medicare requires plan sponsors to establish exceptions and appeals processes with the explicit goal of ensuring good access to needed medications. The burden associated with navigating these processes varies from plan to plan. Part D law also requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.[1] The transition-fill policy is intended to give enrollees time either to find an alternative that is on the plan's formulary or to initiate an exception request.

Plans' formularies and utilization management tools such as prior authorization can help ensure that dispensed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some beneficiaries, these same tools can limit access. Exceptions and appeals processes are designed to find a balance between ensuring access and and appropriateness of the prescription for the beneficiary.

Steps of the exceptions and appeals process

The Part D exceptions and appeals process is complex and involves multiple levels (Figure 14-B1). Typically, the process begins when an enrollee's prescription is rejected at the pharmacy. The pharmacy is required to provide the enrollee with written information about how to obtain a detailed written notice from the enrollee's plan about why the benefit was denied and the right to an appeal. Next, an enrollee (or the enrollee's prescriber or authorized representative) may submit a request to the plan for payment or benefits to which she believes she is entitled.

Part D allows for two kinds of exceptions:

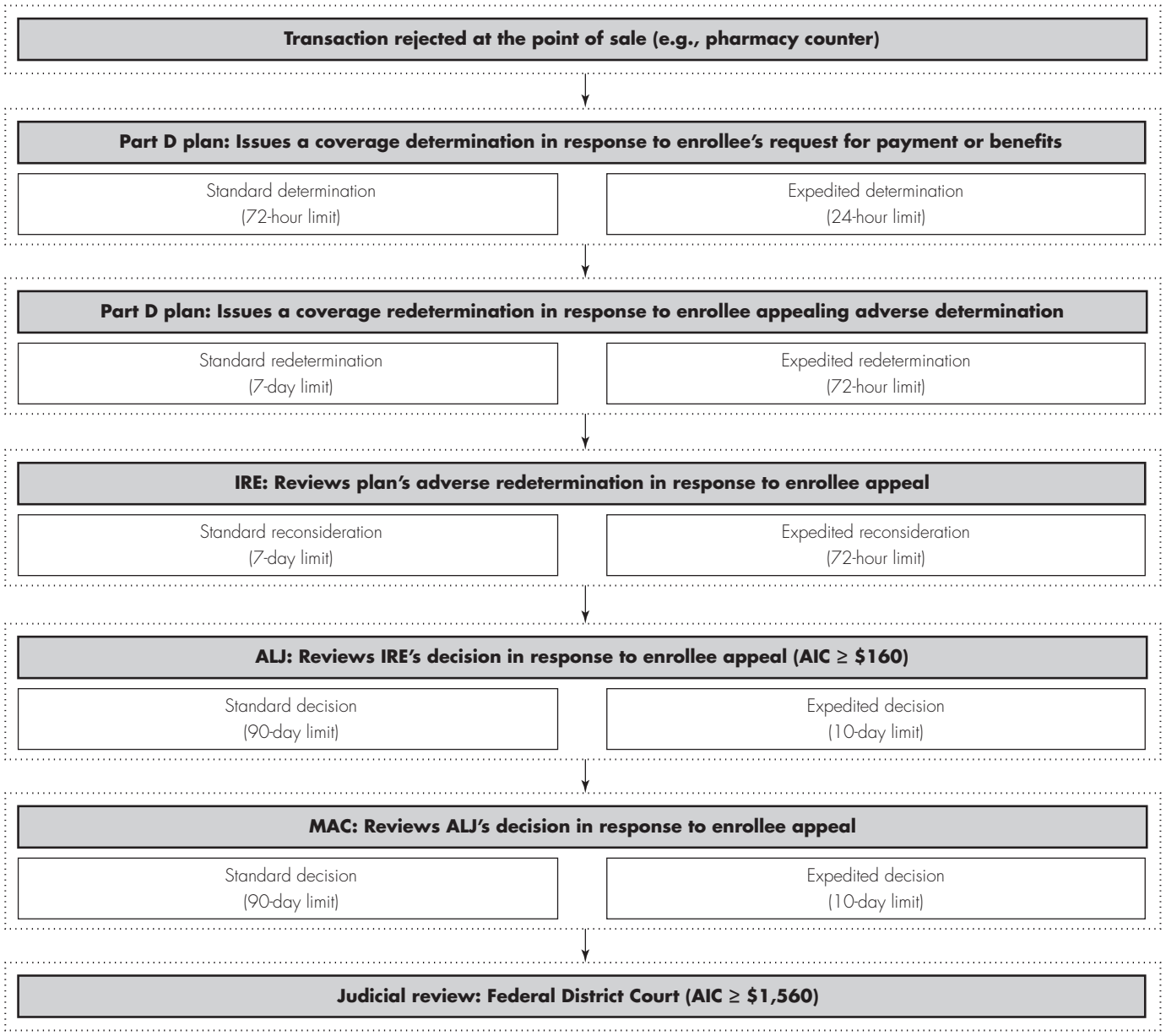
- A "formulary exception" can be requested to obtain a Part D drug that is not included on the plan's formulary or to obtain a formulary drug that is subject to a utilization management restriction (e.g., step therapy, prior authorization, quantity limits) which the enrollee or the enrollee's prescriber believes should not apply.
- A "tiering exception" can be requested to obtain a nonpreferred drug at the lower cost-sharing terms applicable to drugs in a preferred tier when the nonpreferred drug is medically necessary. (Tiering exceptions do not apply to specialty tiers or to low-income subsidy (LIS) copayments. The latter are specified by law rather than part of a plan's benefit design and formulary structure.)

Because exception requests are granted when a plan determines that a requested drug is medically necessary for an enrollee, an enrollee's prescriber must submit a statement to the plan sponsor supporting the request.

Once the request is received, the Part D plan must issue a coverage determination within specified periods. A plan sponsor must provide notice of its coverage determination decision within 24 hours after receiving an expedited request or 72 hours after receiving a standard request (Centers for Medicare & Medicaid Services 2016c). If the enrollee or her prescriber believes that waiting 72 hours

FIGURE 14–B1

Medicare Part D exceptions and appeals process



Note: IRE (independent review entity), ALJ (administrative law judge), AIC (amount in controversy), MAC (Medicare Appeals Council). A request for a coverage determination or an appeal can be submitted by an enrollee, the enrollee's prescribing physician, or the enrollee's authorized representative. AICs shown are for 2017.

Source: Centers for Medicare & Medicaid Services 2016c.

could seriously harm the enrollee's life, health, or ability to regain maximum function, she can request an expedited decision. For requests for benefits, the adjudication time frames do not begin until the enrollee's prescriber submits a supporting statement to the plan sponsor. For payment requests, a plan sponsor must provide written notice of its decision (and make payment when appropriate) within 14 calendar days after receiving a request.

If the plan's review results in a coverage determination that is adverse to the enrollee's request, the enrollee (or the enrollee's prescriber or authorized representative) can then request a redetermination from the plan. Plans are required to inform enrollees of their right to file a redetermination request and their right to be represented by an attorney or other party (Centers for Medicare & Medicaid Services 2014).

The redetermination must be requested within 60 days of the coverage determination (Centers for Medicare & Medicaid Services 2015a). Plan sponsors are required to have procedures for requesting and obtaining information necessary for making timely and appropriate decisions (Centers for Medicare & Medicaid Services 2017c). CMS provides Part D sponsors with best practices such as the recommended number of outreach attempts to prescribers and the timing of outreach attempts.

If dissatisfied with the outcome of the redetermination, the enrollee can ask for reconsideration outside the plan—a review from an independent review entity (IRE). The request must be filed within 60 days of notification of denial from the drug plan (Centers for Medicare & Medicaid Services 2015a). The IRE is required to issue a reconsideration decision notice that contains:

- specific reasons for the entity's decision;
- in the case of an adverse decision, information for the enrollee regarding her right to proceed to an administrative law judge (ALJ) if the claim (e.g., cost of the medication) exceeds the amount in controversy (AIC) threshold; and
- a description of the process for obtaining an ALJ hearing, including the filing location.

In the case of an expedited review, the IRE may present its notice orally as long as a written notification is mailed to the enrollee within three business days (Centers for Medicare & Medicaid Services 2016c).

If the enrollee remains dissatisfied and her case involves an amount that meets a predetermined AIC threshold ($160 in 2017), she may appeal to an ALJ. The enrollee must file a request for a hearing within 60 calendar days of the written notice of a reconsideration. If a plan sponsor receives a request for an ALJ hearing from an enrollee, the plan sponsor must forward the request to the appropriate ALJ office (Centers for Medicare & Medicaid Services 2014).

The next phase of the appeals process is the Medicare Appeals Council (MAC). There is no set amount in question required to proceed to this level of appeal (Centers for Medicare & Medicaid Services 2015a). A request for a review from a MAC must also be filed within 60 calendar days of the receipt of the written ALJ's decision notice. The MAC will limit its evidence review to evidence contained in the record of proceedings before the ALJ and will review any new evidence that relates to the period before the coverage determination (Centers for Medicare & Medicaid Services 2014).

Finally, the enrollee may take her claim to federal district court, as long as the amount in controversy exceeds the specified dollar threshold ($1,560 in 2017). The case must be initiated in the judicial district in which the enrollee lives or the plan sponsor is located. If neither resides in such a judicial district, the case can be filed with the U.S. District Court in Washington, DC.

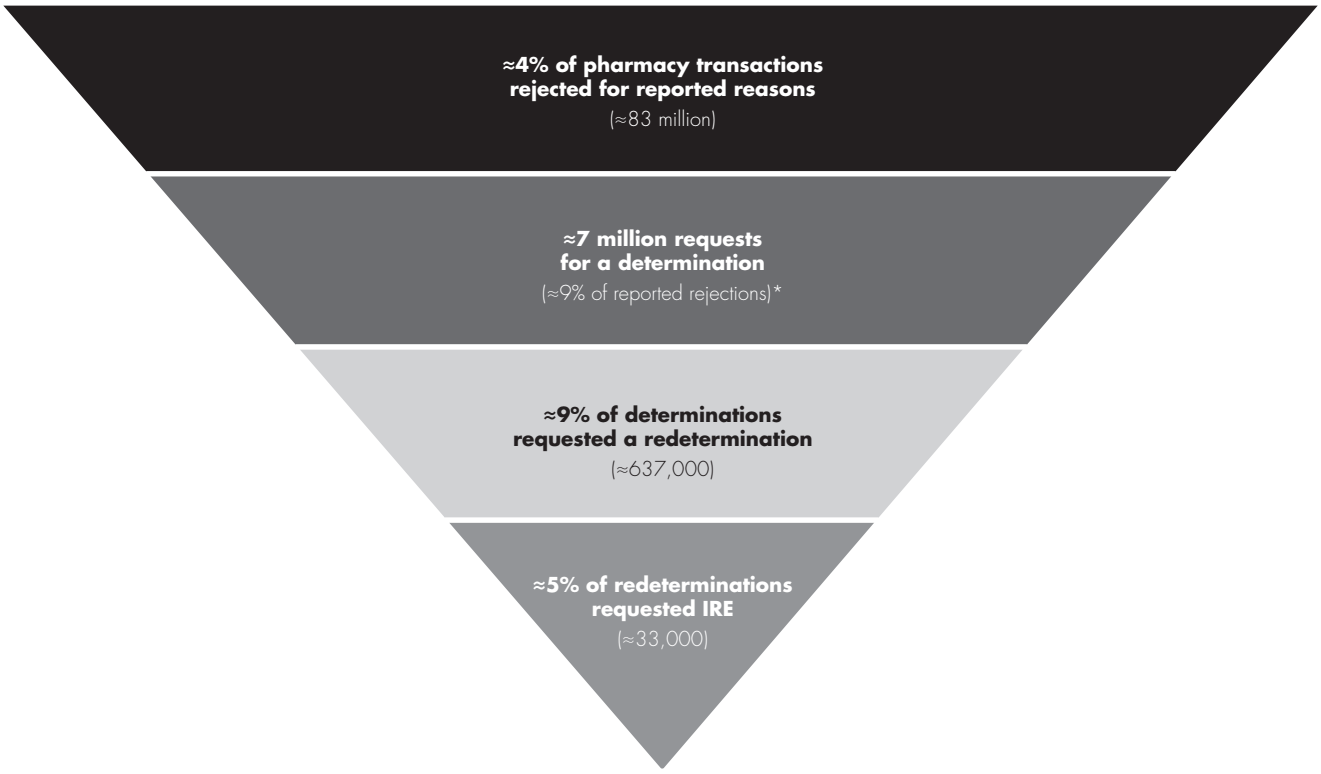
Trends in exceptions and appeals outcomes

Part D plan sponsors are required to report to CMS certain data on pharmacy claims that are rejected at the point of sale as well as outcomes of coverage determinations and redeterminations. Sponsors are not required to report all rejections, but must report rejections associated with nonformulary claims, prior authorizations, step therapy, quantity limits, and certain high-cost edits. CMS also reports on the decisions in the IRE step of the appeals process and uses these data for one measure in Part D plans' star ratings. The plan-reported and IRE data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. Due to the low number of appeals that proceed to the IRE step and issues with the data reported, IRE data are not available or not validated for most plans (74 percent in 2015).

Generally, very few prescriptions are rejected at the pharmacy and far fewer proceed further in the exceptions and appeals process. In 2015, about 4 percent (roughly 83 million) of reported pharmacy transactions were rejected for reported reasons (Figure 14-B2). That share was the same in 2014 and lower (3 percent) in 2013. The most common reason reported for rejection was nonformulary

FIGURE 14–B2

Few reported pharmacy transactions were rejected and appealed, 2015



Note: IRE (independent review entity). The plan-reported and IRE data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. CMS specifically warns that data included in these data files may be incomplete or incorrect. *Although enrollees may request determinations for tiering exceptions, as of 2014, plans are not required to report data on tiering exceptions. In 2013, there were about 141,000 coverage determinations requested for tiering exceptions (3 percent of total coverage determinations).

Source: MedPAC analysis of Centers for Medicare & Medicaid Services data on Part D plan exceptions and appeals data for 2015 and star rating measures for 2017.

status, which affected 1.9 percent of total pharmacy transactions, followed by prior authorization (1.1 percent), quantity limits (0.8 percent), and step therapy (0.1 percent).

In 2015, plans made about 7 million reported coverage determinations—a small fraction (9 percent) of reported rejected pharmacy transactions. Some determinations arise from requests associated with issues other than rejections that are reported, such as for tiering exceptions. Between 2013 and 2015, the overall rate of coverage determinations per 1,000 enrollees increased 35 percent, from 147 per 1,000 enrollees to 199 per 1,000 enrollees (Centers for Medicare & Medicaid Services 2017b). This increase may indicate that enrollees and prescribers are more aware of or more willing to make use of the Part D appeals process or that their prescriptions are increasingly subject to formulary, tiering, and utilization management requirements. In 2015, 64 percent of coverage determination decisions were fully favorable to the enrollee and 36 percent were adverse (Centers for Medicare & Medicaid Services 2017b).

A small fraction (about 9 percent, or 637,000, in 2015) of determination decisions are appealed (or automatically forwarded) for redetermination.[2] Between 2013 and 2015, the overall redetermination rate more than doubled, from 8 per 1,000 enrollees to 17 per 1,000 enrollees (Centers for Medicare & Medicaid Services 2017b). In 2015, nearly 70 percent of redetermination decisions were fully favorable to the enrollee, while less than 1 percent were partially favorable, and 30 percent were adverse.

TABLE 14–B1

Rejections among top 20 combinations of parent organizations and plan types that had the largest number of pharmacy transactions, 2015 (continued next page)

Parent organization	Plan type	Share LIS	Pharmacy transactions (in millions)	Pharmacy transactions rejected	Pharmacy rejections per enrollee
CVS Health Corporation	PDP	50%	342	4%	3.1
UnitedHealth Group Inc.	PDP	24	250	4	1.8
Humana Inc.	PDP	30	184	5	2.2
Humana Inc.	MA–PD	20	121	5	2.1
Aetna Inc.	PDP	47	115	4	3.6
CIGNA	PDP	60	115	3	2.3
Express Scripts Holding Company	PDP	15	114	3	2.0
UnitedHealth Group Inc.	MA–PD	27	105	4	1.6
WellCare Health Plans Inc.	PDP	59	81	4	3.0
Aetna Inc.	MA–PD	12	41	3	2.0
Anthem Inc.	MA–PD	25	33	5	2.7
CIGNA	MA–PD	42	26	3	1.8
WellCare Health Plans Inc.	MA–PD	62	24	4	2.6
Torchmark Corporation	PDP	24	21	3	2.3
Anthem Inc.	PDP	8	21	5	3.0
BCBS MN, MT, NE, ND, WY; Wellmark IA and SD	PDP	3	18	4	2.0
Health Net Inc.	MA–PD	29	18	1	0.9
Health Care Service Corporation	PDP	17	18	6	3.1
InnovaCare Inc.	MA–PD	1	17	5	4.1
Highmark Health	MA–PD	8	14	1	0.4
Top 20 account for share of total			**81%**		
Grand total		**30%**	**2,067**	**4%**	**2.2**

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Potential plan types include PDPs, MA–PDs, employer plans, and Medicare–Medicaid plans, but only MA–PDs and PDPs were among the top 20 combinations. The analysis excludes Kaiser Foundation Health Plan Inc. LIS enrollment average is 24 percent for MA–PD plans and 34 percent for PDPs. Plan-reported data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. CMS specifically warns that data included in these files may be incomplete and/or incorrect.

Source: MedPAC analysis of Centers for Medicare & Medicaid Services data on Part D plan exceptions and appeals data and LIS enrollment for 2015 and star rating measures for 2017.

In turn, an even smaller number of redeterminations are appealed (or auto-forwarded) to the IRE—about 33,000 or 5 percent of redeterminations in 2015. Because the number of actual IRE appeals for each plan is low and problems are found in some submissions, reported data are not available or not validated for the majority of plans (71 percent in 2013 and 74 percent in 2015). When data are reported and validated, the IRE agreed with the plans' redetermination decisions most of the time (on average, 74 percent of the time in 2013 and 82 percent of the time in 2015).

Outcomes at the determination, redetermination, and IRE steps vary substantially at the plan level. To explore this variation, we grouped Part D parent organizations' plans by type—primarily Medicare Advantage–Prescription Drug plans (MA–PDs) and stand-alone prescription drug plans (PDPs)—and focused on the 20 combinations of parent organization plus a specific plan type offered by that parent organization that accounted for the largest number of pharmacy transactions in 2015.[3] Together,

TABLE 14–B1

Rejections among top 20 combinations of parent organizations and plan types that had the largest number of pharmacy transactions, 2015 (cont.)

		Pharmacy transaction rejections						
						High-cost edits		
Parent organization	**Plan type**	**Non-formulary**	**Prior authorization**	**Step therapy**	**Quantity limits**	**Compounds**	**Non-compounds**	**Total (in millions)**
CVS Health Corporation	PDP	56%	28%	0%	15%	0%	0%	13.6
UnitedHealth Group Inc.	PDP	61	18	2	19	0	0	9.5
Humana Inc.	PDP	48	25	2	26	0	0	9.6
Humana Inc.	MA–PD	37	30	3	30	0	0	5.6
Aetna Inc.	PDP	52	34	2	12	0	0	5.0
CIGNA	PDP	47	25	4	24	0	0	3.4
Express Scripts Holding Company	PDP	31	45	14	9	0	0	3.9
UnitedHealth Group Inc.	MA–PD	52	25	1	21	0	0	3.9
WellCare Health Plans Inc.	PDP	72	10	5	13	0	0	3.2
Aetna Inc.	MA–PD	38	41	6	15	0	0	1.3
Anthem Inc.	MA–PD	53	30	3	13	0	1	1.5
CIGNA	MA–PD	48	29	5	17	0	0	0.9
WellCare Health Plans Inc.	MA–PD	65	18	7	11	0	0	0.9
Torchmark Corporation	PDP	51	49	0	0	0	0	0.5
Anthem Inc.	PDP	46	38	4	11	0	1	1.0
BCBS MN, MT, NE, ND, WY; Wellmark IA and SD	PDP	41	29	0	30	0	0	0.6
Health Net Inc.	MA–PD	23	39	7	31	0	0	<0.1
Health Care Service Corporation	PDP	37	34	4	25	0	0	1.1
InnovaCare Inc.	MA–PD	42	28	1	29	0	0	0.9
Highmark Health	MA–PD	42	47	0	11	0	0	0.1
Top 20 account for share of total								**81%**
Grand total		**49%**	**29%**	**3%**	**19%**	**0%**	**0%**	**82.6**

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Potential plan types include PDPs, MA–PDs, employer plans, and Medicare–Medicaid plans, but only MA–PDs and PDPs were among the top 20 combinations. The analysis excludes Kaiser Foundation Health Plan, Inc. LIS enrollment average is 24 percent for MA–PD plans and 34 percent for PDPs. Plan-reported data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. CMS specifically warns that data included in these files may be incomplete and/or incorrect. Percentages may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Centers for Medicare & Medicaid Services data on Part D plan exceptions and appeals data and LIS enrollment for 2015 and star rating measures for 2017.

these 20 combinations accounted for more than 80 percent of total reported pharmacy transactions and rejections, determinations, and redeterminations (Table 14-B1). The combinations varied significantly in the share of their enrollees who received the LIS, ranging from 1 percent for InnovaCare's MA–PDs to 62 percent for WellCare's MA–PDs. The share of pharmacy transactions that were rejected ranged from 1 percent to 6 percent, and pharmacy

TABLE 14–B2

Appeals for determination among top 20 combinations of parent organizations and plan types that had the largest number of pharmacy transactions, 2015

Parent organization	Plan type	Determinations per rejections*	Determinations			
			Fully favorable	Partially favorable	Adverse	Total (in thousands)
CVS Health Corporation	PDP	6%	64%	0%	36%	872.3
UnitedHealth Group Inc.	PDP	11	70	0	33	1,081.6
Humana Inc.	PDP	7	51	1	48	666.5
Humana Inc.	MA–PD	7	57	1	42	391.7
Aetna Inc.	PDP	10	76	0	24	481.0
CIGNA	PDP	14	54	1	45	483.8
Express Scripts Holding Company	PDP	10	73	0	27	380.3
UnitedHealth Group Inc.	MA–PD	12	63	0	37	478.3
WellCare Health Plans Inc.	PDP	1	85	6	9	16.4
Aetna Inc.	MA–PD	14	70	0	30	184.6
Anthem Inc.	MA–PD	9	87	0	13	136.4
CIGNA	MA–PD	8	52	0	47	66.2
WellCare Health Plans Inc.	MA–PD	8	31	2	57	71.6
Torchmark Corporation	PDP	14	69	0	31	75.8
Anthem Inc.	PDP	10	86	0	14	107.1
BCBS MN, MT, NE, ND, WY; Wellmark IA and SD	PDP	15	59	0	41	99.7
Health Net Inc.	MA–PD	16	69	0	31	35.3
Health Care Service Corporation	PDP	8	72	0	28	82.0
InnovaCare Inc.	MA–PD	9	62	0	38	73.3
Highmark Health	MA–PD	20	53	0	47	19.1
Top 20 account for share of total						**81%**
Grand total		**9%**	**67%**	**0%**	**34%**	**7,156.4**

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Potential plan types include PDPs, MA–PDs, employer plans, and Medicare–Medicaid plans, but only MA–PDs and PDPs were among the top 20 combinations. The analysis excludes Kaiser Foundation Health Plan Inc. Plan-reported data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. CMS specifically warns that data included in these files may be incomplete and/or incorrect. Percentages may not sum to 100 percent due to rounding.
*Determinations may be in response to enrollee and prescribers' requests that are not associated with reported pharmacy transaction rejections, most notably for tier exceptions.

Source: MedPAC analysis of Centers for Medicare & Medicaid Services data on Part D plan exceptions and appeals data for 2015 and star rating measures for 2017.

transaction rejections per enrollee ranged from 0.4 to 4.1. Reasons for rejection were concentrated among nonformulary status, prior-authorization requirements, and quantity limits, but with varying ratios by plan (Table 14-B1, p. 13). The share of pharmacy transaction rejections that were appealed for determination ranged from 1 percent to 20 percent (Table 14-B2). The share of adverse determination decisions that were appealed for redetermination ranged from 2 percent to 26 percent (Table 14-B3). Even among the 20 parent organization–plan type combinations that accounted for the largest number of pharmacy transactions, many plans did not

TABLE 14–B3

Appeals for redetermination among top 20 combinations of parent organizations and plan types that had the largest number of pharmacy transactions, 2015

			Redeterminations				IRE
Parent organization	**Plan type**	**Redeterminations as a share of total determinations***	**Fully favorable**	**Partially favorable**	**Adverse**	**Total (in thousands)**	**Percent upheld**
CVS Health Corporation	PDP	9%	52%	0%	48%	82.0	85%
UnitedHealth Group Inc.	PDP	10	71	0	28	107.8	66%–95%
Humana Inc.	PDP	9	84	1	15	59.1	DV
Humana Inc.	MA–PD	8	83	1	16	32.5	DV
Aetna Inc.	PDP	6	77	0	22	26.7	92%
CIGNA	PDP	15	94	0	6	74.5	DV
Express Scripts Holding Company	PDP	7	71	0	29	27.4	DV
UnitedHealth Group Inc.	MA–PD	10	76	1	23	49.8	N/A & 76%–100%
WellCare Health Plans Inc.	PDP	26	96	1	3	28.6	73%
Aetna Inc.	MA–PD	7	72	0	28	12.0	N/A & 82%–100%
Anthem Inc.	MA–PD	2	66	0	34	2.1	N/A & 61%–91%
CIGNA	MA–PD	13	92	0	5	8.6	DV & N/A
WellCare Health Plans Inc.	MA–PD	9	96	1	2	6.6	N/A & 53%–83%
Torchmark Corporation	PDP	10	62	0	38	7.4	N/A
Anthem Inc.	PDP	2	61	1	38	1.8	N/A & 84%
BCBS MN, MT, NE, ND, WY; Wellmark IA and SD	PDP	11	64	0	36	10.6	83%
Health Net Inc.	MA–PD	3	40	1	59	1.2	N/A
Health Care Service Corporation	PDP	7	63	0	37	6.0	87%
InnovaCare Inc.	MA–PD	2	84	0	16	1.3	N/A & 77%
Highmark Health	MA–PD	9	48	0	52	1.7	N/A & 66%–72%
Top 20 account for share of total						**86%**	
Grand total		**9%**	**74%**	**0%**	**26%**	**637.2**	

Note: IRE (independent review entity), DV (data validation), N/A (not available), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Potential plan types include PDP, MA–PD, employer, and Medicare–Medicaid plans, but only MA–PDs and PDPs were among the top 20 combinations. The analysis excludes Kaiser Foundation Health Plan Inc. "N/A" means not enough data available, no data available, and/or plan too new to be measured. "DV" indicates that CMS identified issues with this plan's data that preclude publication of results. Plan-reported data are incomplete and should be interpreted with caution. Not all Part D plan data must be reported, and some that are reported do not pass data validation requirements. CMS specifically warns that data included in these data files may be incomplete and/or incorrect.
*Determinations may be in response to enrollee and prescribers requests that are not associated reported pharmacy transaction rejections, most notably for tier exceptions.

Source: MedPAC analysis of Centers for Medicare & Medicaid Services data on Part D plan exceptions and appeals data for 2015 and star rating measures for 2017.

have data available or their data did not pass validation at the IRE step. In cases for which data were available and validated, the share of plans' redetermination decisions that the IRE upheld varied from 53 percent to 100 percent (Table 14-B3).

Stakeholder concerns about the exceptions and appeals process

Stakeholders—beneficiary advocates, prescribers, plan sponsors, and CMS—have noted frustrations with Part D exceptions and appeals. Part D requires quicker adjudication time frames than does Medicare Advantage for medical benefits because "the majority of Part D coverage requests involve prescription drugs an enrollee has not yet received, which increases the risk of adverse clinical outcomes if access to the drug is delayed" (Centers for Medicare & Medicaid Services 2016a). Plan sponsors must make decisions within specified time periods, but report difficulties reaching prescribers. If the plan contacts the prescriber but is not able to obtain the supporting information needed within the allotted time, the plan must issue a denial and then process any subsequent information it receives as a redetermination. Similarly, if the plan is unable to complete a coverage redetermination in time, the plan must forward the case to the IRE. At the same time, determination and redetermination outcomes that skew to overturning plans' coverage decisions would undermine plans' efforts to manage drug utilization.

CMS audits have found that Part D plans have difficulties in the areas of coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2017a, Centers for Medicare & Medicaid Services 2015b). CMS has repeatedly expressed concern that some Part D sponsors reject claims inappropriately and are not fully compliant with transition-fill requirements (Centers for Medicare & Medicaid Services 2015b, Centers for Medicare & Medicaid Services 2012, Centers for Medicare & Medicaid Services 2010). The agency has applied civil and monetary sanctions against several plan sponsors for failure to comply with regulations in areas such as formulary requirements, coverage determinations, and exceptions and appeals processes (Centers for Medicare & Medicaid Services 2017a, Centers for Medicare & Medicaid Services 2016b).

Beneficiaries who participated in the Commission's focus groups often described different strategies they used when their medications were not covered by their plans or the cost-sharing amounts were very expensive. For example, they reported asking the pharmacist whether it was possible to substitute with generic versions, went back to their doctors to find alternatives or get samples, or paid for the drug out of pocket. A few reported not filling the prescription. Among the few who had tried to appeal a plan's decision, the results were mixed.

Beneficiary advocates have recommended providing enrollees with information about the reason for a plan denial at the point of sale (Medicare Rights Center 2016b). Instead, the notice given to enrollees by the pharmacy when their transaction is rejected tells them of their right to request a coverage determination and instructs them (or their prescriber) to contact their plan. Plans are required to provide enrollees with detailed information in a standard form in the case of an adverse coverage determination or redetermination.[4] There may be obstacles to getting detailed information to enrollees at the pharmacy in the case of a rejection, such as privacy regulations, standards about the amount of information included along with the rejection code, and the ability and willingness of pharmacies to produce completed forms tailored to individual enrollees.

In 2016, CMS tested various approaches to help beneficiaries acquire an appropriate medication. Plans that participated in the pilot found the tested processes to be labor intensive, possibly taking even more time than the regular exception and appeals process, and thus not scalable. It turned out that some pharmacy transaction rejections were the result of the practice of "pinging" the system to check current price or cost-sharing amounts. All participants found that the key difficulty appeared to be reaching and engaging prescribers (Centers for Medicare & Medicaid Services 2016d). Some noted that including extra time in the pilot model to contact prescribers was beneficial.

Multiple stakeholders have noted that a more efficient approach would be to resolve issues at the point of prescribing through electronic prescribing (eRx), real-time prescription benefit check, and electronic prior authorization (ePA) rather than at the pharmacy counter. Such tools could reduce the need for coverage determinations and appeals and could increase the likelihood that beneficiaries receive an appropriate medication. Automated processes could also lower administrative burden and lead to a more uniform approach for beneficiaries, prescribers, and plans (American Medical Association 2015). While beneficiary advocates are generally supportive of such steps, some contend those measures would not be sufficient to address persistent challenges (Medicare Rights Center 2016a).

Electronic prior authorization and similar tools have the potential to reduce the need for enrollees to use the

exceptions and appeals process, but there are obstacles to their full adoption. By law, Part D sponsors must support eRx, but it remains optional for physicians and pharmacies, and there are no existing statutory requirements for ePA. Adoption across multiple stakeholders—Part D plans, pharmacy benefit managers, pharmacies, and clinicians—is necessary for ePA to have its full beneficial effect. However, the coordination and integration of dozens of ePA software packages with hundreds of electronic health record platforms is technically challenging. In addition, ePA developers must include work-arounds for situations when one or more of the stakeholders essential to an ePA transaction does not use the software (e.g., offering retrospective functionality so that pharmacies can initiate ePA when the prescriber submitted a script outside the system). Perhaps the most essential requirement for adoption of ePA is clinician acceptance and use, which can require paying fees and embracing practice pattern change. ■

Endnotes

1 The transition fill is a temporary one-time supply of up to 30 days of medication provided during the first 90 days in a plan for new enrollees and during the first 90 days of the new contract year for existing enrollees. For individuals living in long-term care facilities, the temporary supply may be for up to 31 days and may be renewed as necessary during the entire length of the 90-day transition period.

2 In cases where the plan does not arrive at a determination or redetermination within the specified time periods, the appeal is automatically forwarded to the redetermination or IRE steps, respectively.

3 Potential plan types include PDPs, MA–PDs, employer plans, and Medicare–Medicaid plans, but only MA–PDs and PDPs were among the top 20 combinations. We excluded Kaiser Foundation Health Plan Inc. because it generally has an "open formulary" but relies on other utilization management requirements, especially prior authorization.

4 The standard notice provides a specific and detailed explanation of why the plan arrived at an adverse coverage determination for the prescription drug, as well as a description of what information is needed to approve coverage. If the drug is one that could ultimately be approved, the notice must explicitly state the need for a prescriber's supporting statement and clearly identify the type of information that should be submitted. In addition, CMS instructs plans to include excerpts from their formularies, where applicable, including detailed clinical information related to the plan's coverage criteria for the requested drug.

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