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**Office of Inspector General**



# Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending

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## Why OIG Did This Review

In the last decade, Medicare Part D and its beneficiaries spent billions of dollars on revolutionary yet costly hepatitis C drugs. In response to concerns over the affordability of hepatitis C treatments, drug manufacturer Gilead introduced authorized generic versions of two of its brand-name hepatitis C drugs in 2019 (authorized generics are brand-name drugs that are sold without the brand name on their label). Despite the availability of these authorized generics, as well as other lower-cost brand options, preliminary research suggested that Part D beneficiaries continued to be more likely to use higher-cost hepatitis C drugs than Medicaid beneficiaries, leading to higher spending in Part D. Reflecting on OIG's goal of identifying opportunities to lower prescription drug spending for patients and programs, we conducted this review to explore possible incentives created by Part D's programmatic structure that may be influencing use of higher-cost hepatitis C drugs in Medicare.

## How OIG Did This Review

We used claims data to compare utilization of hepatitis C drugs in Medicare Part D to utilization in Medicaid in 2019 and 2020. We also compared inclusion of higher-cost versus lower-cost hepatitis C drugs in 2020 Part D plan formularies. We then examined the effects utilization trends have on Medicare and beneficiary spending.

# Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending

## Key Takeaway

Medicare beneficiaries are much less likely to receive lower-cost versions of the same drugs (i.e., authorized generics)—as well as other widely-used lower-cost brand-name drugs—to treat hepatitis C. Part D's programmatic structure may lead to plan sponsors preferring higher-cost versions, resulting in beneficiaries paying thousands more out-of-pocket and nearly double Medicare reinsurance.

## What OIG Found

Following the introduction of authorized generic versions of two brand-name hepatitis C drugs—Eplclusa and Harvoni—in 2019, use of the authorized generic versions increased in Medicaid at greater rates than in Medicare Part D. In 2020, some Part D plans did not cover the identical authorized generics, limiting beneficiary access to less costly options. Medicare beneficiaries also were less likely to use other lower-cost brand-name options in 2020 compared to Medicaid beneficiaries.

Although rebates from manufacturers reduced overall Part D spending for higher-cost hepatitis C drugs (such as Eplclusa and Harvoni), they provided little relief to beneficiaries or the Medicare program. Part D beneficiaries without financial assistance paid, on average, \$2,200 more out of pocket for higher-cost hepatitis C drugs in 2020. Further, Medicare's average catastrophic coverage payment for a beneficiary prescribed a higher-cost drug was over \$8,000 more compared to a beneficiary prescribed a lower-cost drug. As a result, Medicare spent \$155 million more in catastrophic coverage payments for higher-cost hepatitis C drugs, despite a similar number of beneficiaries in each cost group reaching catastrophic coverage.

OIG's findings about utilization trends for higher-cost hepatitis C drugs in Medicare align with experts' suggestions that certain programmatic factors, such as manufacturer rebates, may be providing incentives for Part D plan sponsors to prefer that their enrollees use higher-cost drugs.

## What OIG Recommends and How the Agency Responded

We recommend that—to reduce out-of-pocket costs for beneficiaries and combat rising drug spending in Medicare Part D—the Centers for Medicare & Medicaid Services (CMS) encourage Part D plans to increase access to and use of the authorized generic versions of Eplclusa and Harvoni, within the authorities granted under statute. We also recommend that CMS pursue additional strategies—such as educating providers and pharmacies—to increase access to and use of lower-cost hepatitis C drugs in Medicare Part D. CMS concurred with both of our recommendations.

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# BACKGROUND

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## OBJECTIVES

1. To compare utilization of lower-cost hepatitis C drugs between Medicare Part D and Medicaid, focusing particularly on the authorized generic versions of Epclusa and Harvoni.
  2. To identify programmatic factors that may be contributing to observed utilization patterns of higher-cost drugs in Part D.
  3. To examine the spending difference between higher-cost and lower-cost hepatitis C drugs for Part D and beneficiaries.
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In 2020, Medicare Part D spent roughly \$1.6 billion for drugs used to treat more than 34,000 beneficiaries with chronic hepatitis C—a liver infection that can lead to life-threatening conditions if untreated.<sup>1, 2</sup> With the approval of Harvoni in 2014, direct-acting antiviral drugs that can clear the hepatitis C virus from the body (hereinafter referred to as “hepatitis C drugs”) became the standard treatment for chronic hepatitis C.<sup>3</sup> Although lifesaving, hepatitis C drugs such as Harvoni and Epclusa (approved in 2016) have list prices exceeding \$70,000 per 12-week course of treatment, raising concerns about their financial impact on patients and payers.<sup>4, 5, 6</sup>

In 2019, after a number of lower-priced brand-name hepatitis C drugs were approved, Gilead—the manufacturer of Epclusa and Harvoni—launched authorized generic versions of both drugs with the expressed goal of reducing patients’ out-of-pocket costs.<sup>7</sup> Authorized generics are identical to approved brand-name drugs but are sold without the brand name on their label.<sup>8</sup> Preliminary research found that utilization in Medicaid and commercial plans shifted to the lower-cost brand-name and authorized generic versions; however, a proportionate shift did not occur in Medicare Part D.<sup>9</sup>

Because a portion of drug costs in Part D is shared by beneficiaries, many hepatitis C patients covered under Medicare could be incurring thousands of dollars more in out-of-pocket costs than if they had been prescribed less expensive options. This report provides details about the comparative financial impact of higher-cost hepatitis C drugs on the Part D program in 2020 while discussing possible incentives for Part D plan sponsors to prefer higher-cost drugs.

## Medicare Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act established the Medicare Part D program in 2006 to provide Medicare beneficiaries with optional outpatient prescription drug coverage.<sup>10</sup> Under contracts with the Centers for

Medicare & Medicaid Services (CMS), private companies, known as Part D plan sponsors, provide competing prescription drug plans to enrolled beneficiaries.<sup>11</sup> Plan sponsors and CMS share risk for beneficiary drug expenditures.<sup>12</sup> Sponsors, pharmacy benefit managers, drug manufacturers, and pharmacies negotiate drug prices, reimbursement amounts, and rebates privately in Part D. Federal law prohibits CMS from interfering in these negotiations.<sup>13</sup>

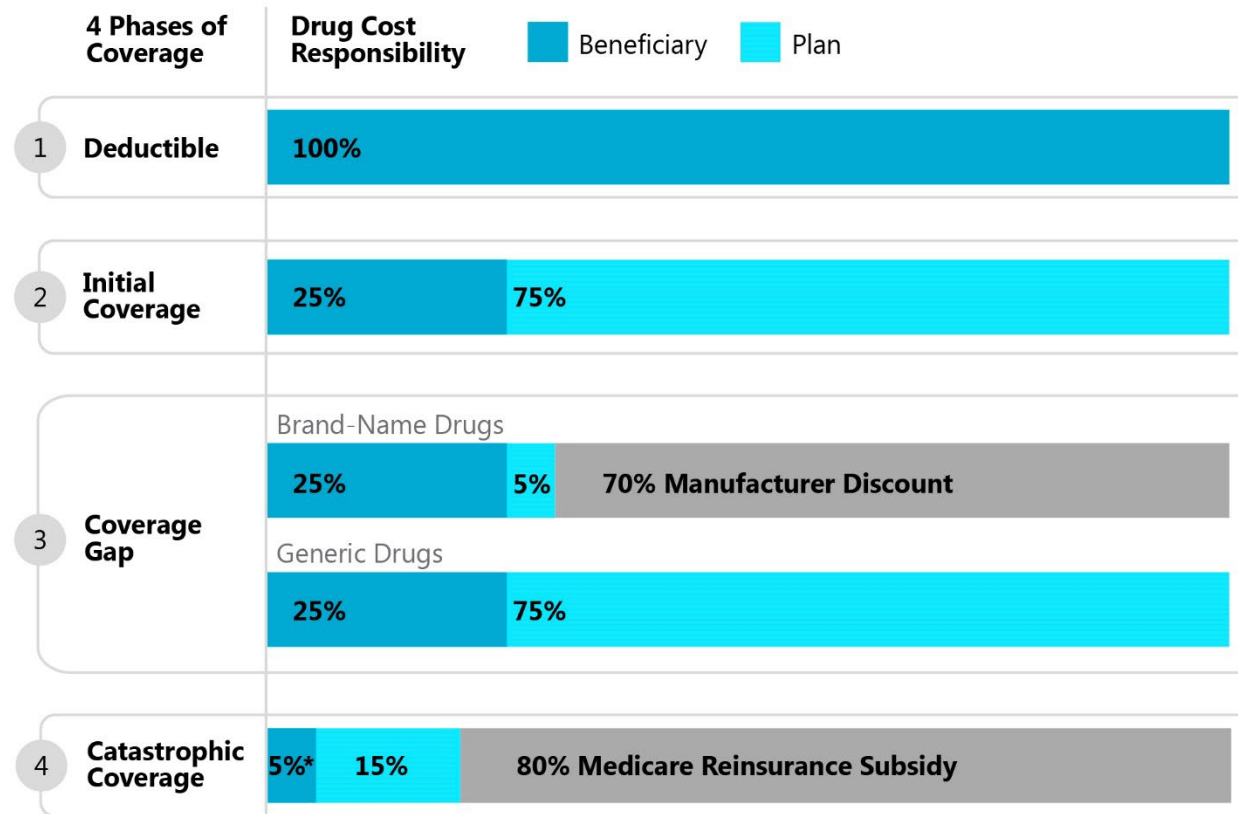
Part D plans must offer certain minimum prescription drug benefits as specified by Federal law, but beneficiary cost-sharing, coverage of specific drugs, and other benefit details may vary between plans.<sup>14</sup> Sponsors typically develop a list of covered drugs, known as a formulary, for their plans.<sup>15</sup> Formularies often exclude certain drugs or give preference to others by placing them on lower beneficiary cost-sharing tiers than other competing therapies that treat the same condition.<sup>16</sup> CMS is prohibited from requiring a particular formulary for the reimbursement of covered Part D drugs.<sup>17</sup> However, CMS exercises its authority to review Part D plan formularies to ensure that drug plans do not substantially discourage enrollment by certain Part D eligible individuals.<sup>18</sup>

## Standard Part D benefit

Part D plan designs vary, but sponsors must offer coverage that either meets or is “actuarially equivalent” to the parameters of the standard Part D benefit established annually by Medicare.<sup>19</sup> The standard benefit is composed of the following four cost-sharing phases: (1) deductible, (2) initial coverage, (3) coverage gap, and (4) catastrophic coverage (see Exhibit 1). Each year, beneficiaries start at the first phase and progress through the successive phases as their pre-rebate drug costs increase beyond certain thresholds.

Exhibit 1: Each year, beneficiaries progress through the four phases of the standard Part D benefit as their prescription drug spending increases.

**There is no cap on beneficiary out-of-pocket costs.**



Source: 42 CFR § 423.104 and OIG analysis of data from CMS, “Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.”

Note: Figures displayed are based on the parameters of the 2020 standard Part D benefit for enrollees without the low-income subsidy (LIS). Benefit details and beneficiary cost-sharing vary in most plans, but all coverage offered by Part D sponsors must be actuarially equivalent to the standard benefit.

\*Note: Beneficiary liability in catastrophic coverage is the greater of 5% of a drug’s cost or \$3.60 for generic/multisource drugs and \$8.95 for other drugs.

### Part D cost-sharing

In Part D, most beneficiaries are responsible for a portion of their drug costs. Generally, their remaining drug costs are paid by plan sponsors or Medicare subsidies.<sup>20</sup> Beneficiary cost-sharing obligations, including deductibles, copayments, and coinsurance, are collectively referred to as “out-of-pocket” costs.<sup>21</sup> Out-of-pocket costs vary depending on specific plan designs, eligibility for the low-income subsidy (LIS), the price of the drug being purchased, and the beneficiary’s current phase of Part D coverage.<sup>22</sup> Because beneficiaries’ cost-sharing amounts are often based on a drug’s list price, higher-cost drugs typically result in greater out-of-pocket costs.<sup>23</sup> Generally, beneficiaries’ out-of-pocket spending is not capped in Part D.<sup>24</sup>

Medicare subsidizes coverage for beneficiaries with incomes up to 150 percent of the poverty level through the LIS.<sup>25</sup> Other sources such as State pharmaceutical assistance programs, charities, or group health plans may reduce beneficiaries' out-of-pocket liability.<sup>26</sup>

**Cost-sharing for LIS beneficiaries.** Cost-sharing for beneficiaries receiving the LIS—including premiums, deductibles, coinsurance, and copayments—are fully or partially subsidized by Medicare depending on the beneficiary's level of eligibility (see Appendix A for details). The cost-sharing parameters in the coverage gap also differ—notably, plan sponsors bear no cost-sharing liability and manufacturers are not required to discount brand-name drugs (as is required for non-LIS enrollees).<sup>27</sup> Sixty-nine percent of Part D beneficiaries who were treated with hepatitis C drugs in 2020 received the LIS.<sup>28, 29</sup>

## Medicare payments to plans

Medicare pays a portion of its Part D costs through two subsidies provided monthly to plan sponsors: (1) direct subsidies and (2) reinsurance subsidies.<sup>30</sup> Direct subsidies are based on sponsors' estimates of the cost to provide Part D coverage.<sup>31</sup> Reinsurance subsidies—the largest and fastest-growing portion of Part D costs—cover Medicare's approximately 80-percent liability for drug costs in catastrophic coverage.<sup>32, 33</sup> After the end of the year, either sponsors pay overestimates of their costs back to Medicare or Medicare provides additional payments for underestimated costs—this process is known as reconciliation.<sup>34</sup>

## Part D rebates

Plan sponsors or pharmacy benefit managers frequently receive compensation after the point of sale that alters the final price they pay for Part D drugs. Referred to as direct and indirect remuneration (DIR), this compensation decreases the costs incurred under Part D plans.<sup>35</sup> Manufacturer rebates—post-sale price concessions received by sponsors or pharmacy benefit managers—comprise a significant portion of DIR. Often, manufacturers offer higher rebates to sponsors and pharmacy benefit managers in exchange for favoring their drugs over competing therapies on plan formularies. Rebate amounts are usually calculated as a percentage of a drug's list price, meaning higher-cost drugs are typically associated with larger rebates.<sup>36</sup>

Rebates can significantly reduce Part D sponsors' net spending for drugs; however, because rebates are paid to plans after a prescription has been picked up by the beneficiary, they do not directly lower beneficiary cost-sharing.<sup>37, 38</sup> Although rebates do not reduce out-of-pocket costs for individual beneficiaries at the point of sale, they are taken into account when CMS calculates beneficiary premiums for the following year.<sup>39</sup> As a result, savings from rebates and other DIR place downward pressure on premiums paid by enrollees and subsidized by Medicare.<sup>40, 41, 42</sup> Recent policy proposals attempting to pass rebate savings along to Part D beneficiaries at the point of sale have faced criticism for their potential to increase premiums.<sup>43, 44</sup>



## Prescription Drug Treatments for Hepatitis C

Harvoni, the first complete hepatitis C treatment taken via a daily pill approved by the U.S. Food and Drug Administration (FDA), entered the market in 2014 with a list price of \$94,500 for the standard course of treatment.<sup>45</sup> In 2016 and 2017, several other brand-name hepatitis C drugs reached the market, including Epclusa (with a list price of \$74,760) and the substantially lower-cost Mavyret (with a list price of \$26,400 per treatment).<sup>46, 47</sup> In 2019, the manufacturer of Epclusa and Harvoni, Gilead Sciences, launched authorized generic versions of both drugs nearly a decade before the brand patents were set to expire, explaining that the large rebates offered to payers for Epclusa and Harvoni were not lowering costs for patients. The list prices for the authorized generic versions (\$24,000 per treatment) were roughly 70 percent less than those of the brand-name versions.<sup>48, 49, 50</sup>

### Authorized generics in Medicare Part D

An authorized generic drug is a brand-name drug that is sold by (or on behalf of) the brand-name manufacturer without using the brand-name label. Unlike generic drugs that may differ from brand-name drugs in inactive ingredients, authorized generics are the same drug as their corresponding branded products. A generic drug requires FDA approval under an Abbreviated New Drug Application; however, an authorized generic can be introduced at any time under the brand-name product's existing New Drug Application, regardless of patent status.<sup>51</sup> Authorized generics are subject to the brand-name discount provided by manufacturers in the coverage gap phase of the Part D benefit.

### Coverage of hepatitis C drugs in Medicare Part D and Medicaid

Substituting lower-priced generics that are therapeutically equivalent to higher-cost brand-name drugs has become a key strategy for lowering drug spending in the U.S.<sup>52</sup> However, stakeholders and policy experts have raised concerns that elements of Part D's current programmatic structure potentially provide incentives for sponsors to prefer higher-cost drugs with large rebates over less costly alternatives (e.g., preferring the brand-name versions of Epclusa and Harvoni over their authorized generics).<sup>53, 54, 55, 56</sup> In Part D, plan sponsors can use formulary coverage and tier placement to encourage Medicare beneficiaries to use certain hepatitis C drugs over others in exchange for larger rebates.

Unlike in Part D—where rebates are negotiated among plan sponsors, drug manufacturers, and pharmacies—rebate amounts for drugs reimbursed under Medicaid are set by statute.<sup>57</sup> In addition to these statutory rebates, State Medicaid agencies also have authority to negotiate supplemental rebate agreements with drug manufacturers. State Medicaid programs utilize drug placement on their Preferred Drug Lists as a tool to negotiate higher supplemental rebates. Preferred Drug Lists create incentives for prescribers and beneficiaries to choose certain drugs—typically lower-cost drugs—when multiple treatment options are available.<sup>58</sup> For example,



many States currently list lower-cost drugs such as Mavyret or the Epclusa authorized generic as preferred direct-acting antiviral treatments for hepatitis C.<sup>59</sup>

## Methodology

### Scope

In this study, OIG examined utilization trends of hepatitis C direct-acting antiviral drugs (i.e., Harvoni, Epclusa, their authorized generic versions, and other brand-name products) in Medicare Part D and Medicaid in 2019 and 2020.

### Data analysis

**Identifying hepatitis C drugs and categorizing them by cost group.** We identified all hepatitis C direct-acting antivirals (hepatitis C drugs) that were approved by FDA as of April 29, 2021. We then removed hepatitis C drugs (1) that were discontinued by their manufacturer or (2) for which no Medicare Part D or Medicaid claims were paid in 2019 or 2020. We ranked the remaining hepatitis C drugs by their list prices for a typical course of treatment.<sup>60</sup> We categorized the drugs into two cost groups: (1) lower-cost hepatitis C drugs and (2) higher-cost hepatitis C drugs. Four drugs (including the Mavyret and the authorized generic versions of Epclusa and Harvoni) with list prices ranging from approximately \$22,000 to \$36,000 per treatment comprised the lower-cost hepatitis C drug cost group. The higher-cost hepatitis C drug cost group included four drugs with list prices ranging from approximately \$75,000 to \$95,000 per treatment.

**Determining utilization of hepatitis C drugs in Part D and Medicaid.** Using Part D prescription drug event (PDE) data, we calculated the proportions of Part D beneficiaries who initiated treatment using the authorized generic versions of Epclusa and Harvoni in each quarter of 2019 and 2020. To do this, we divided the number of beneficiaries who received the authorized generic versions by the total number of beneficiaries who received the brand-name or authorized generic versions for both Epclusa and Harvoni. We repeated this analysis using Transformed Medicaid Statistical Information System (T-MSIS) data to determine the same proportions of Medicaid beneficiaries.

Beyond solely comparing Epclusa and Harvoni with their authorized generic versions, we also expanded our analysis to include utilization rates among additional lower- and higher-cost products. Specifically, we calculated the proportion of Part D beneficiaries who received (1) one of the two lower-cost brand products, (2) one of the two lower-cost authorized generic versions, or (3) one of the four higher-cost hepatitis C drugs in each quarter of 2019 and 2020 by dividing the number of beneficiaries in each of those groups by the total number of beneficiaries who received hepatitis C drugs. We repeated this analysis using T-MSIS data to determine the same proportions of Medicaid beneficiaries.

**Formulary inclusion of hepatitis C authorized generics.** We used formulary data obtained from CMS to count the number of Part D plans that included Epclusa or Harvoni but not their authorized generics in their 2020 formularies. We then divided the result by the total number of plans that covered Epclusa or Harvoni in 2020. We used the formulary and PDE data to determine the number of beneficiaries who initiated treatment using the brand-name version of Epclusa or Harvoni while being enrolled in a plan that covered only the brand-name versions and the number of beneficiaries who initiated treatment using the using the brand-name versions while being enrolled in a plan that covered both the brand-name and authorized generic versions.

**Calculating average post-DIR Part D spending per beneficiary for hepatitis C drugs.** For both the lower-cost and higher-cost groups, we subtracted total DIR—including manufacturer rebates—received by Part D plan sponsors from total gross Part D spending to determine net spending per cost group. We then divided net spending by the number of beneficiaries who received higher or lower-cost hepatitis C drugs to calculate average post-DIR Part D spending per beneficiary for lower-cost and higher-cost hepatitis C drugs. Because rebate information is confidential, our relevant analysis and findings are presented in general terms that conceal specific rebate amounts for individual drugs.

**Calculating average beneficiary out-of-pocket spending for hepatitis C drugs.** We analyzed average beneficiary out-of-pocket spending for higher-cost and lower-cost hepatitis C drugs for two groups of beneficiaries: (1) beneficiaries who received any form of financial assistance (e.g., the LIS, support from charities or group health plans, etc.) and (2) beneficiaries who received no Part D financial assistance. We calculated 2020 average beneficiary out-of-pocket spending for lower-cost hepatitis C drugs for each of the financial assistance groups by dividing the summed patient costs for each group (as reported in the PDE data) by the number of beneficiaries in each group who received lower-cost hepatitis C drugs. We repeated this calculation for beneficiaries who received higher-cost hepatitis C drugs. We calculated the difference between average beneficiary out-of-pocket spending for higher-cost and lower-cost hepatitis C drugs to estimate potential spending reductions for beneficiaries who could switch from higher-cost to lower-cost drugs.

**Calculating spending for hepatitis C drugs in catastrophic coverage.** For beneficiaries who entered catastrophic coverage in 2020, we calculated Medicare's reinsurance amounts after rebates for higher-cost and lower-cost hepatitis C drugs. We calculated Medicare's average catastrophic coverage payment for a beneficiary that received a lower-cost hepatitis C drug by dividing the summed Medicare reinsurance costs by the number of beneficiaries who reached the catastrophic coverage phase. We repeated this calculation for beneficiaries who received higher-cost hepatitis C drugs.

**Literature review on incentives created by Part D's program structure.** We conducted internet searches to locate and review research conducted by policy

experts about Part D programmatic features that may be contributing to differing utilization rates for higher-cost hepatitis C drugs in Part D compared to other payers.

See the Detailed Methodology section for more information.

## Limitations

Our estimated calculations of potential spending reductions for Medicare and beneficiaries if more beneficiaries received lower-cost versions of hepatitis C drugs did not account for how drug manufacturers or Part D plan sponsors may respond to increased utilization of lower-cost drugs. We did not review medical records, and therefore, our analysis does not account for the possibility that certain beneficiaries may have a medical need for a specific hepatitis C drug. Further, this study did not consider how increased use of lower-cost hepatitis C drugs would shift Part D and beneficiary financial liability through the Part D benefit phases.

## Standards

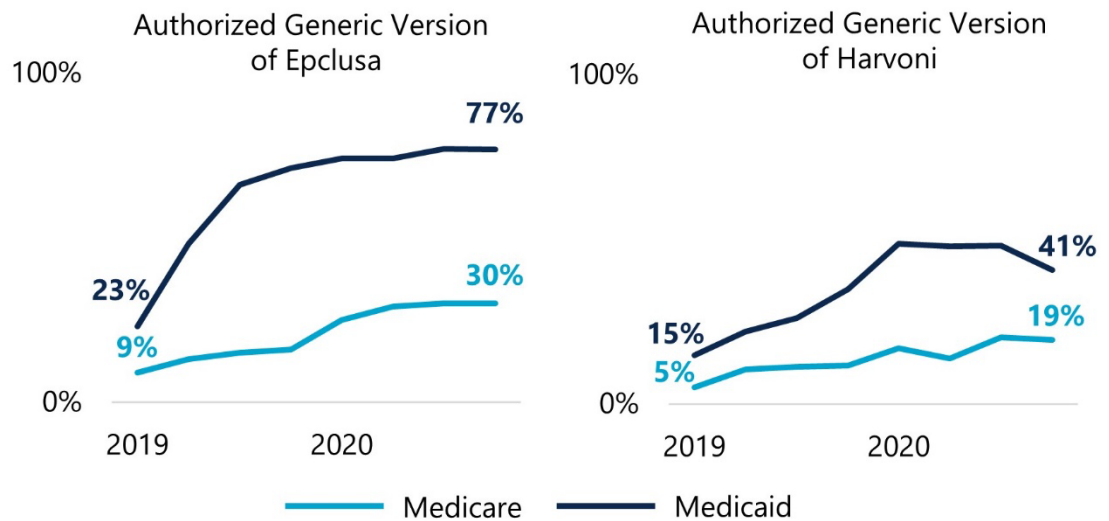
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

# FINDINGS

**Through 2019 and 2020, the use of authorized generics to treat hepatitis C grew steadily in both Medicare and Medicaid; however, Medicare beneficiaries were still much more likely to be prescribed the brand-name counterparts**

In January 2019, the manufacturer of Epclusa and Harvoni launched authorized generic versions of both drugs with the expressed goal of lowering patient costs.<sup>61</sup> In the initial quarter of availability, less than 10 percent of Medicare patients and under 25 percent of Medicaid patients who initiated treatment with Epclusa, Harvoni, or their authorized generics received the lower-cost versions. Through the end of 2020, authorized generic use increased in both programs, though Medicare still lagged far behind Medicaid (see Exhibit 2).

**Exhibit 2: At the end of 2020, a much greater proportion of Medicaid beneficiaries than Medicare beneficiaries received authorized generic versions of Epclusa and Harvoni rather than the brand-name versions.**



Source: OIG analysis of 2019 and 2020 Medicare Part D PDE records and T-MSIS data.

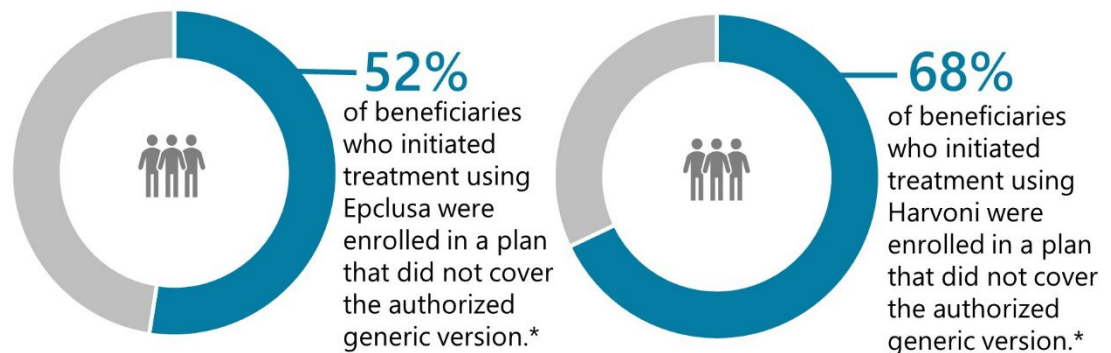
Specifically, in the last quarter of 2020, approximately 5,700 Medicaid beneficiaries initiated treatment with Epclusa or its identical authorized generic. More than three-quarters (77 percent) of these patients received the lower-cost authorized generic option. In contrast, less than a third (30 percent) of the 3,800 Medicare beneficiaries fitting the same criteria received the authorized generic version. Similarly, the Harvoni authorized generic was even less likely to be used in place of the brand-name version (see Exhibit 2). Notably, the utilization rate of these two

authorized generic versions among Medicare beneficiaries is considerably lower than Part D's 90 percent overall utilization rate of generic drugs.<sup>62</sup>

## Lack of formulary inclusion among Part D plans is likely a primary factor in the relatively low use of authorized generics to treat hepatitis C in Medicare

Stakeholders have expressed concerns that the large rebates associated with higher-cost drugs, such as Epclusa and Harvoni, create incentives for plan sponsors to prefer drugs with larger rebates on their plan formularies.<sup>63, 64</sup> In 2020, nearly half of Part D plans covered Epclusa or Harvoni but did not cover the authorized generic versions that were specifically launched to reduce patient costs. The lack of coverage may largely explain why so few Medicare beneficiaries received an authorized generic to treat hepatitis C in 2020, and instead so many received the more expensive brand-name version. Half of Medicare Part D beneficiaries who initiated treatment with Epclusa in 2020 were enrolled in a plan that covered Epclusa but not its authorized generic. Similarly, nearly two-thirds of Part D beneficiaries who received their first dose of Harvoni in 2020 were enrolled in a plan that covered the brand-name version but not the authorized generic version (see Exhibit 3).

**Exhibit 3: More than half of Part D beneficiaries who initiated treatment using the brand-name version of Epclusa or Harvoni in 2020 were enrolled in plans that did not cover the authorized generic versions—limiting access to less expensive yet identical versions of the same drugs.**



Source: OIG analysis of formulary inclusion of authorized generic drugs, Epclusa, and Harvoni, 2022.

\*Note: We removed a small number of beneficiaries from our analysis who initiated treatment using the brand-name version of Epclusa or Harvoni in 2020 and were enrolled in a plan that covered neither the brand-name nor the authorized generic versions.

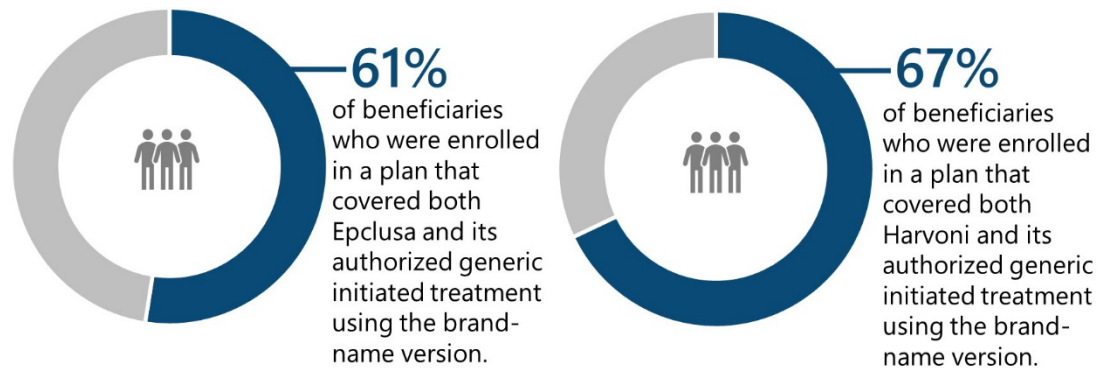
## Barriers beyond formulary inclusion, such as prescriber habits and drug substitution practices, may also be limiting beneficiary access to lower-cost authorized generic versions

Even among Medicare beneficiaries enrolled in plans that included both the brand-name and authorized generic versions of Epclusa or Harvoni, the majority still

received the higher-cost option. Six out of ten beneficiaries who were enrolled in such plans initiated treatment with Epclusa rather than its authorized generic, as did two-thirds of beneficiaries who received a version of Harvoni (see Exhibit 4). In a number of cases, this may have been the result of specific instructions from the prescriber. In 2020, approximately one in five prescriptions for Epclusa or Harvoni paid under Medicare included a “dispense as written” note from the prescriber prohibiting the pharmacist from substituting the equivalent authorized generic version.

Even in the absence of prescriber instruction, pharmacy substitution practices vary due to State laws. Although some States require pharmacists to provide a generic equivalent (if available) in place of the prescribed brand, generic substitution is not a mandatory practice in most States.<sup>65, 66</sup>

**Exhibit 4: A majority of Part D beneficiaries who were enrolled in plans that covered both the brand-name and authorized generic versions of Epclusa or Harvoni were treated with the higher-cost brand-name versions in 2020.**



Source: OIG analysis of formulary inclusion of authorized generic drugs, Epclusa, and Harvoni, 2022.

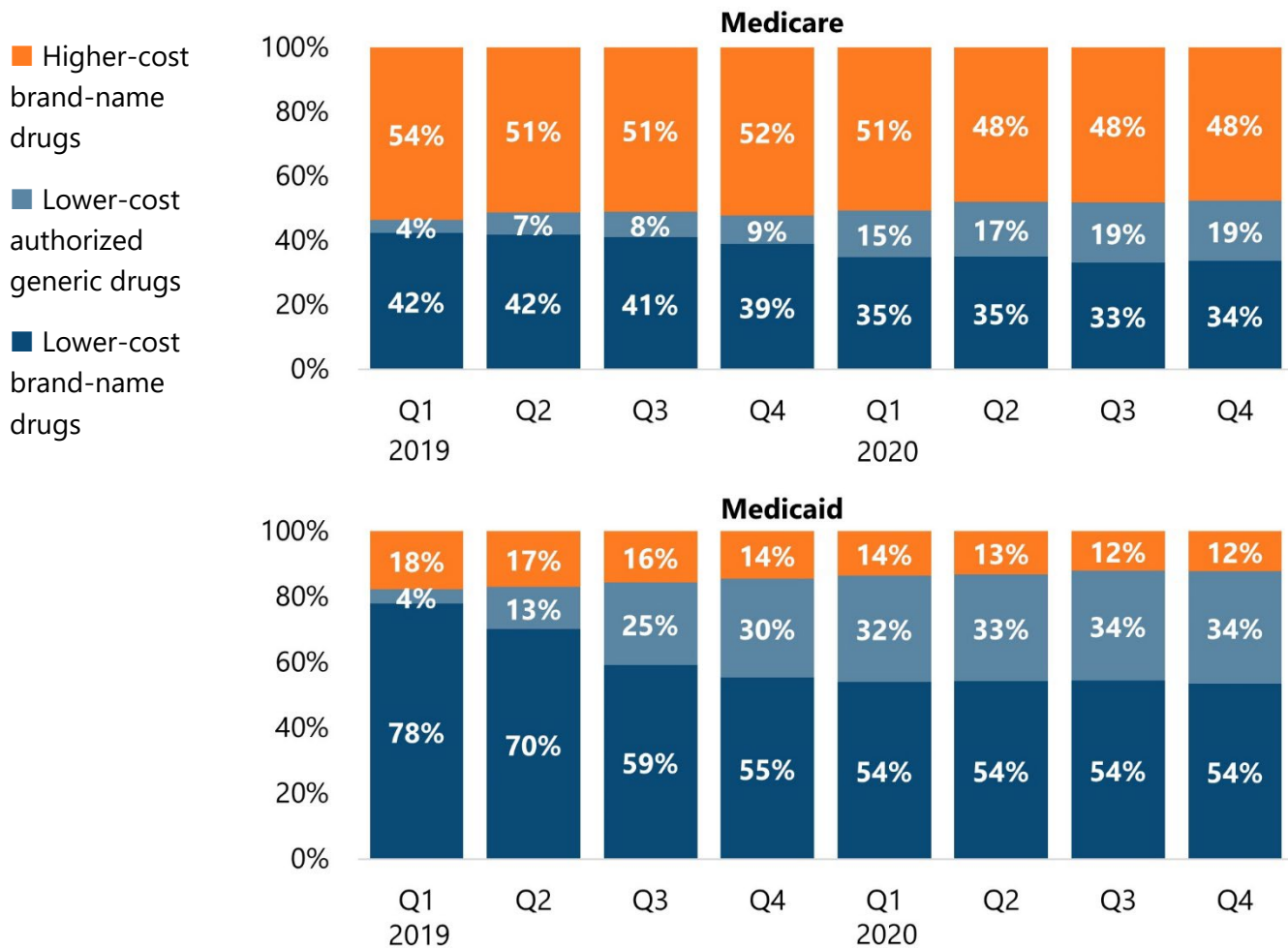
## **In addition to being well ahead of Medicare in the adoption of authorized generics to treat hepatitis C, Medicaid utilization of lower-cost brands far surpassed Medicare utilization**

Prior to the introduction of authorized generics, another brand-name product with a substantially lower list price than Epclusa and Harvoni was already on the market and widely prescribed in Part D and Medicaid.<sup>67</sup> Mavyret—approved in 2017 and marketed as the only 8-week cure for all six basic genotypes of hepatitis C for those new to treatment—had a list price of \$26,400 per treatment in 2020—approximately one-third to one-fourth that of Epclusa and Harvoni.<sup>68, 69</sup> Because Mavyret is approved to treat all genotypes of hepatitis C, the drug is widely recognized as a potentially lower-cost alternative to higher-cost brands.<sup>70, 71, 72</sup>

However, as was the case with authorized generics, Medicare beneficiaries were much less likely to utilize lower-cost brand-name options, including Mavyret. During the first quarter of 2019 (the same quarter in which the authorized generics reached the

market), 78 percent of Medicaid beneficiaries who initiated treatment with a hepatitis C drug were already receiving a lower-cost brand-name version compared to only 42 percent of Medicare Part D beneficiaries (see Exhibit 5). In subsequent quarters, the increased utilization of authorized generics in both programs often came at the expense of the lower-cost brands rather than Eplclusa or Harvoni. By the end of 2020, utilization of these lower-cost brand-name hepatitis C drugs decreased to 54 percent and 34 percent in Medicaid and Medicare, respectively. In total, the availability of authorized generics resulted in a net decrease of just 6 percentage points in the number of beneficiaries receiving higher-cost hepatitis C drugs in both Medicare and Medicaid (see Appendix B).

**Exhibit 5: The introduction of authorized generics slightly reduced patient utilization of higher-cost brand-name drugs in Medicare and Medicaid, but most of their growth came from reduced utilization of lower-cost brand-name drugs.**



Source: OIG analysis of 2019 and 2020 Medicare Part D PDE records and T-MSIS data.  
 Note: Total of percentages for each quarter may not equal 100 due to rounding.



## The large rebates offered by manufacturers for higher-cost hepatitis C drugs benefit plan sponsors but provide little relief to beneficiaries who received the drugs or the Medicare program

Large rebates provided by manufacturers for higher-cost drugs covered under Part D allow plan sponsors to recoup much of their gross spending. In turn, lower net spending allows plans to offer lower premiums and attract enrollees.<sup>73, 74</sup> However, policy experts have raised concerns that the reduction in net sponsor spending for higher-cost drugs caused by large rebates has weakened sponsors' incentives to negotiate lower prices.<sup>75</sup>

In 2020, manufacturer rebates—among other DIR received by plan sponsors after the point of sale—significantly reduced the difference in net Part D spending per beneficiary between higher-cost and lower-cost hepatitis C drugs. On average, gross Part D spending for the four higher-cost hepatitis C drugs used in 2020 exceeded \$65,000 per beneficiary, compared to roughly \$25,000 for the four lower-cost hepatitis C drugs. Once DIR—primarily in the form of rebates—is taken into account, net expenditures for the higher-cost drugs averaged less than \$30,000 per beneficiary, a reduction of more than 50 percent. In contrast, DIR for lower-cost versions was much smaller, resulting in a net cost of \$21,000 per beneficiary. In other words, after rebates and other post-sale price concessions, the net cost difference between higher-cost and lower-cost hepatitis C drugs plummeted from more than \$40,000 per patient to less than \$10,000 per patient.

### Because beneficiary cost-sharing is based on pre-rebate prices, the use of higher-cost hepatitis C drugs in Part D led to thousands of dollars in additional costs for some Medicare beneficiaries

Twenty-six percent of Part D beneficiaries who were treated with hepatitis C drugs in 2020 did not receive the LIS or other assistance (e.g., support from State pharmaceutical assistance programs, charities, group health plans, etc.). Because cost-sharing under Part D is based on pre-DIR drug prices, beneficiaries without any form of assistance who received a higher-cost drug to treat hepatitis C paid almost 70 percent more in out-of-pocket costs over their course of treatment than similar beneficiaries who received lower-cost drugs (\$5,300 versus \$3,100, see Exhibit 6).

**Exhibit 6: Medicare Part D beneficiaries who did not receive financial assistance paid, on average, \$2,200 more out of pocket for higher-cost hepatitis C drugs.**



Source: OIG analysis of 2020 Medicare Part D PDE records.

Additionally, use of higher-cost hepatitis C drugs contributed to higher Medicare spending on cost-sharing subsidies for LIS beneficiaries. Nearly three-quarters of the Medicare Part D beneficiaries who received hepatitis C drugs in 2020 were eligible for the LIS or other assistance that reduced their out-of-pocket costs. On average, the beneficiaries who received the LIS or other assistance paid nominal amounts for their hepatitis C drugs, regardless of whether they were prescribed higher-cost or lower-cost versions (see Appendix C). However, although differences in out-of-pocket costs between higher-cost and lower-cost versions may be negligible for these individual beneficiaries, the LIS is by definition a “subsidy” and is ultimately funded by taxpayers.

**After rebates, Medicare’s average catastrophic coverage payment for a beneficiary prescribed a higher-cost hepatitis C drug was nearly double that of a beneficiary prescribed a lower-cost drug**

Given the high cost of treatment, nearly all Part D beneficiaries receiving hepatitis C drugs entered catastrophic coverage in 2020, at a cost of nearly \$539 million to Medicare.<sup>76</sup> The portion of total hepatitis C drug costs that were incurred in catastrophic coverage—the benefit phase in which Medicare’s liability is 80 percent—was much larger for beneficiaries taking higher-cost versions. After rebates and any other applicable DIR, Medicare’s final catastrophic coverage payments for higher-cost hepatitis C drugs totaled \$347 million in 2020, compared to only \$192 million for lower-cost versions, despite a similar number of beneficiaries reaching catastrophic coverage in each cost group (see Exhibit 7).<sup>77</sup> Medicare’s average catastrophic coverage payment for a beneficiary prescribed a higher-cost drug to treat hepatitis C was more than \$20,000—nearly double that of a beneficiary prescribed a lower-cost drug which averaged slightly more than \$11,000.

Plans’ 15-percent financial obligation in the catastrophic coverage phase is much lower than Medicare’s 80 percent. The reduced plan liability in catastrophic coverage may lead sponsors to prefer higher-cost drugs that push beneficiaries into catastrophic coverage faster—especially because higher-cost drugs are typically associated with larger rebates.<sup>78, 79</sup>

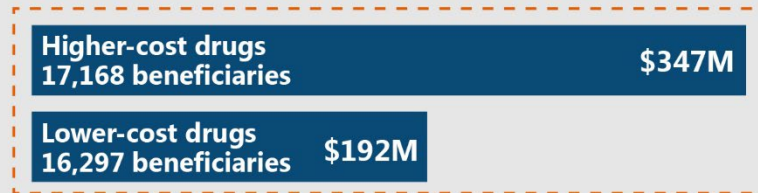
Exhibit 7: After rebates, Medicare reinsurance spending was \$155 million more for higher-cost hepatitis C drugs despite a similar number of beneficiaries reaching catastrophic coverage in each cost group.

#### 4 Phases of Coverage

1. Deductible
2. Initial Coverage
3. Coverage Gap

#### 4. Catastrophic Coverage

##### 2020 Medicare Reinsurance Totals After Rebates\*



Medicare reinsurance spending was **\$155 million more** for higher-cost hepatitis C drugs.

\*Medicare's reinsurance pays for 80% of catastrophic spending.

Source: OIG analysis of 2020 Medicare Part D PDE records and DIR data.

# CONCLUSION AND RECOMMENDATIONS

In the last decade, a new class of drugs have revolutionized treatment of chronic hepatitis C. These modern hepatitis C drugs have proved to be life-saving; however, their high costs have financially strained patients and payers. Although less expensive hepatitis C drugs have gradually entered the market, almost half of Medicare beneficiaries continued to use higher-cost options in 2020, a rate several times higher than for Medicaid. These discrepancies were reflected in lower Medicare utilization rates for both the authorized generic versions of Eplclusa and Harvoni—lower-cost versions marketed without the brand label—as well as for lower-cost brand-name drugs that treat the same hepatitis C genotypes. Many Part D plans did not include authorized generic versions in their formularies, limiting beneficiaries' ability to access less costly treatment options.

Certain factors related to Part D's programmatic structure help explain why plan sponsors may prefer higher-cost versions. Higher-cost drugs push beneficiaries into catastrophic coverage earlier where plans' financial obligation is only 15 percent—much lower than Medicare's 80 percent. Additionally, the large rebates provided by manufacturers for higher-cost hepatitis C drugs can significantly reduce Part D sponsors' net spending. The savings plans receive from rebates can be used by plans to offer Medicare beneficiaries lower premiums and attract more enrollees.

Although large rebates benefit plans and place downward pressure on premiums, they do little to alleviate the extra costs paid by beneficiaries and Medicare for higher-cost hepatitis C drugs. Medicare beneficiaries who were not eligible for the LIS or other financial assistance would have spent an average of \$2,200 less in out-of-pocket costs had they used lower-cost hepatitis C drugs.<sup>80</sup> Further, use of higher-cost versions among beneficiaries who received the LIS increased Medicare's taxpayer-funded subsidy spending. Even after rebates, Medicare paid \$155 million more in catastrophic coverage reinsurance payments for higher-cost hepatitis C drugs—spending that could have been reduced if more beneficiaries had used lower-cost options.

OIG recognizes that CMS's authorities to address the issues raised in this report are limited. As outlined in the Social Security Act, CMS is strictly prohibited from interfering with the negotiations between drug manufacturers, pharmacies, and Part D plans. In addition, the agency may not require a particular formulary for the reimbursement of covered Part D drugs. However, given the substantial costs of certain widely used hepatitis C drugs for beneficiaries and Medicare, OIG believes CMS can still take a number of limited steps to promote the use of lower-cost versions—some of which are identical to the brand-name drug product. Therefore, we recommend that—to reduce out-of-pocket costs for beneficiaries and combat rising drug spending in Medicare Part D—CMS:

## Encourage Part D plans to increase access to and use of the authorized generic versions of Epclusa and Harvoni, within the authorities granted under statute

CMS should encourage Part D plans to increase access to and use of the authorized generic versions of Epclusa and Harvoni within its authority. For example, CMS could:

- Develop a voluntary innovation model through its Center for Medicare and Medicaid Innovation that seeks to increase use of authorized generic hepatitis C drugs over brand-name versions. In 2021, CMS concluded the Part D Payment Modernization Model which attempted to decrease Part D program spending by creating new incentives for program participants to choose drugs with lower list prices.<sup>81</sup> Acknowledging the complexities of these voluntary models, CMS could redevelop aspects of the 2021 model, such as allowing participating sponsors to reduce or eliminate beneficiary copayments for lower-cost drugs, into a new demonstration focused on substituting authorized generics versions of Epclusa and Harvoni for their brand-name versions and possibly increasing use of other lower-cost brand-name hepatitis C drugs. While the Center for Medicare and Medicaid Innovation’s models generally do not focus on a specific drug used for a limited time period, CMS could evaluate whether developing such a model would be appropriate given that Part D and its beneficiaries spent more than \$1.6 billion on hepatitis C drugs in 2020.
- Monitor Part D plans’ submitted formularies to examine coverage trends of the relatively new authorized generic versions of Epclusa and Harvoni. Specifically, CMS could consider determining whether formulary coverage of the authorized generic versions increases as they become more entrenched in the hepatitis C treatment market. When plans include the brand-name versions but elect not to cover the identical yet significantly less expensive authorized generic versions, enrollees are limited in their ability to access the more affordable authorized generic versions. As part of its formulary review process, CMS could therefore consider identifying formularies that continue to include the brand-name versions while excluding the authorized generic versions. The results of monitoring this coverage could inform CMS’s efforts to—within its authority—encourage access to authorized generic versions.

## Pursue additional strategies—such as educating providers and pharmacies—to increase access to and use of lower-cost hepatitis C drugs in Medicare Part D

CMS should pursue strategies to increase beneficiary access to and use of lower-cost hepatitis C drugs in Part D. For example, CMS could educate providers and

pharmacies—as frontline workers interacting with beneficiaries who will be treated with these drugs—on the availability, safety, and value of the authorized generic versions of Epclusa and Harvoni. Specifically, the Part D beneficiaries enrolled in plans that cover both the brand-name and authorized generic versions of Epclusa or Harvoni represent the patient population that could gain the most from educated providers and pharmacists discussing less expensive but pharmaceutically identical options. In addition, even beneficiaries enrolled in plans that lack authorized generic coverage may benefit from their providers discussing other lower-cost brand-name treatment options. To increase use of lower-cost hepatitis C drugs in Medicare, both providers and patients must be well informed of the availability and safety of lower-cost options such as authorized generics. Pharmacies must also be aware of and stock lower-cost options.

# AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with both of OIG's recommendations.

In response to our first recommendation, CMS stated that it is committed to taking action, as appropriate, to increase access to and use of lower-cost drug products, including authorized generics. CMS indicated that it intends to examine how its Center for Medicare and Medicaid Innovation models could be used to test methods to lower beneficiary and program spending on drugs and incentivize the use of authorized generic drugs. Regarding OIG's second suggestion for CMS to examine coverage trends of the authorized generic versions of Epclusa and Harvoni among Part D formularies, CMS stated that its authority to review Part D plan formularies centers on ensuring that plans provide access to medically necessary treatments and do not discriminate against particular types of beneficiaries. Because authorized generic drugs are the same drugs as their brand-name counterparts (without the brand-name label), CMS indicated that monitoring whether or not they are included on formularies would not have an effect on access to medically necessary treatments nor allow CMS to take action within the authorities granted under statute. OIG encourages CMS to continue to explore appropriate actions the agency could take to encourage Part D plan sponsors to increase access to and use of lower-cost hepatitis C drugs.

In response to our second recommendation, CMS stated that it will look to pursue additional strategies to increase access to and use of lower-cost drugs, including hepatitis C authorized generics, in Part D.

OIG appreciates CMS's commitment to work within its authority to address both cost and access concerns to ensure that Medicare beneficiaries have access to high-quality and affordable health care.

For the full text of CMS's comments, see the Agency Comments appendix at the end of the report.



# DETAILED METHODOLOGY

**Identifying hepatitis C drugs.** We first obtained all National Drug Codes (NDCs) associated with hepatitis C direct-acting antivirals (hereinafter referred to as “hepatitis C drugs”) approved by FDA as of April 29, 2021, from manufacturer websites. We then used NDC data and Medicare Part D/Medicaid claims data to identify FDA-approved hepatitis C drugs for which claims were paid under Medicare or Medicaid in 2019 or 2020. We removed NDCs from our list of hepatitis C drugs that have been discontinued or for which no Medicare or Medicaid claims were paid in 2019 or 2020.

**Categorizing hepatitis C drugs by cost group.** We ranked the hepatitis C drugs for which claims were paid under Medicare Part D or Medicaid in 2019 or 2020 by their list prices for a typical course of treatment. To do this, we obtained quarterly list prices (i.e., wholesale acquisition costs) per pill for each hepatitis C drug from the First Databank drug compendia. Using manufacturer websites, we then determined that the most common length of treatment for the hepatitis C drugs in our study was 12 weeks, except for Mavyret which has a typical treatment length of 8 weeks. We then multiplied the list prices per pill by the number of pills required for a typical course of treatment to determine the cost per treatment for each hepatitis C drug. We categorized the drugs into two groups according to their cost per treatment: (1) lower-cost hepatitis C drugs and (2) higher-cost hepatitis C drugs. Four drugs (including the authorized generic versions of Harvoni and Epclusa) with treatment list prices ranging from approximately \$22,000 to \$36,000 comprised the lower-cost hepatitis C drug cost group. The higher-cost hepatitis C drug cost group included four drugs with list prices ranging from approximately \$75,000 to \$95,000 per treatment.

**Determining utilization of hepatitis C drugs in Part D and Medicaid.** Every time a beneficiary fills a prescription in Part D, a sponsor must submit a prescription drug event (PDE) record to CMS. We used PDE data to count the number of Part D beneficiaries who initiated hepatitis C treatment (i.e., received the first dose of a hepatitis C drug) in 2019 and 2020. For a given analysis year, we removed beneficiaries who had a claim for a hepatitis C drug in the prior year (i.e., they were not initiating treatment in our analysis year). By counting beneficiaries’ initial treatment, we controlled for potential differences in treatment length (e.g., 8 weeks vs. 12 weeks) and differences in prescribing (e.g., 30-day supply vs. 90-day supply). We also removed beneficiaries who used more than one hepatitis C drug (i.e., switched hepatitis C drugs), representing 2 percent of beneficiaries in both 2019 and 2020.

We calculated the proportions of Part D beneficiaries who initiated treatment using the authorized generic versions of Epclusa and Harvoni in each quarter of 2019 and 2020 by dividing the number of beneficiaries who received the authorized generic

versions by the total number of beneficiaries who received the brand-name or authorized generic versions for both Epclusa and Harvoni. We repeated this analysis using T-MSIS data to determine the same proportions of Medicaid beneficiaries.

Beyond solely comparing Epclusa and Harvoni with their authorized generic versions, we also expanded our analysis to include utilization rates among additional lower- and higher-cost products. Specifically, we calculated the proportion of Part D beneficiaries who received (1) one of the two lower-cost brand products, (2) one of the two lower-cost authorized generic versions, or (3) one of the four higher-cost hepatitis C drugs in each quarter of 2019 and 2020 by dividing the number of beneficiaries in each of those groups by the total number of beneficiaries who received hepatitis C drugs. We repeated this analysis using T-MSIS data to determine the same proportions of Medicaid beneficiaries.

**Formulary inclusion of hepatitis C drugs.** To determine formulary inclusion trends of hepatitis C drugs, we counted the number of Part D plans that included Epclusa or Harvoni but not their authorized generics in their formularies in 2020. We then divided the result by the total number of plans that covered Epclusa or Harvoni in 2020 to calculate the proportion of total plans that covered Epclusa or Harvoni without covering their authorized generic versions. We used the formulary and PDE data to determine the number of beneficiaries who initiated treatment using the brand-name version of Epclusa or Harvoni while being enrolled in a plan that covered only the brand-name versions as well as the number of beneficiaries who initiated treatment using the brand-name versions while being enrolled in a plan that covered both the brand-name and authorized generic versions.

**Calculating average post-DIR Part D spending per beneficiary for hepatitis C drugs.** We obtained 2020 direct and indirect remuneration (DIR) data from CMS's Health Plan Management System. For both the lower-cost and higher-cost hepatitis C drugs cost groups, we subtracted total DIR—including manufacturer rebates—received by Part D plan sponsors from total gross Part D spending to determine net spending per cost group. We then divided net spending by the number of beneficiaries who received lower-cost or higher-cost hepatitis C drugs to calculate average post-DIR Part D spending per beneficiary for lower-cost and higher-cost hepatitis C drugs. Because rebate information is confidential, our relevant analysis and findings are presented in general terms that conceal specific rebate amounts for individual drugs.

**Calculating average beneficiary out-of-pocket spending for hepatitis C drugs.** We analyzed average beneficiary out-of-pocket spending for higher-cost and lower-cost hepatitis C drugs for two groups of beneficiaries: (1) beneficiaries who received any form of financial assistance (e.g., the low-income subsidy, support from charities or group health plans, etc.) and (2) beneficiaries who received no Part D financial assistance. We calculated 2020 average beneficiary out-of-pocket spending for lower-cost hepatitis C drugs for each of the financial assistance groups by dividing the summed patient costs for each group (as reported in the PDE data) by the number of beneficiaries in each group who received lower-cost hepatitis C drugs. We repeated

this calculation for beneficiaries who received higher-cost hepatitis C drugs. See Appendix C for additional details on the financial assistance groups' composition and out-of-pocket costs. We calculated the difference between average beneficiary out-of-pocket spending for higher-cost and lower-cost hepatitis C drugs to estimate potential spending reductions for beneficiaries who could switch from higher-cost to lower-cost drugs.

**Calculating spending for hepatitis C drugs in catastrophic coverage.** For beneficiaries who entered catastrophic coverage in 2020, we calculated Medicare's reinsurance amounts in catastrophic coverage after rebates for higher-cost and lower-cost hepatitis C drugs. We calculated Medicare's average catastrophic coverage payment for a beneficiary that received a lower-cost hepatitis C drug by dividing the summed Medicare reinsurance costs by the number of beneficiaries who reached the catastrophic coverage phase. We repeated this calculation for beneficiaries who received higher-cost hepatitis C drugs.

**Literature review on incentives created by Part D's program structure.** We conducted internet searches to locate and review research conducted by policy experts about Part D programmatic features (e.g., financial incentives created by rebates) that may be contributing to differing utilization rates for higher-cost hepatitis C drugs in Part D compared to other payers.

# APPENDICES

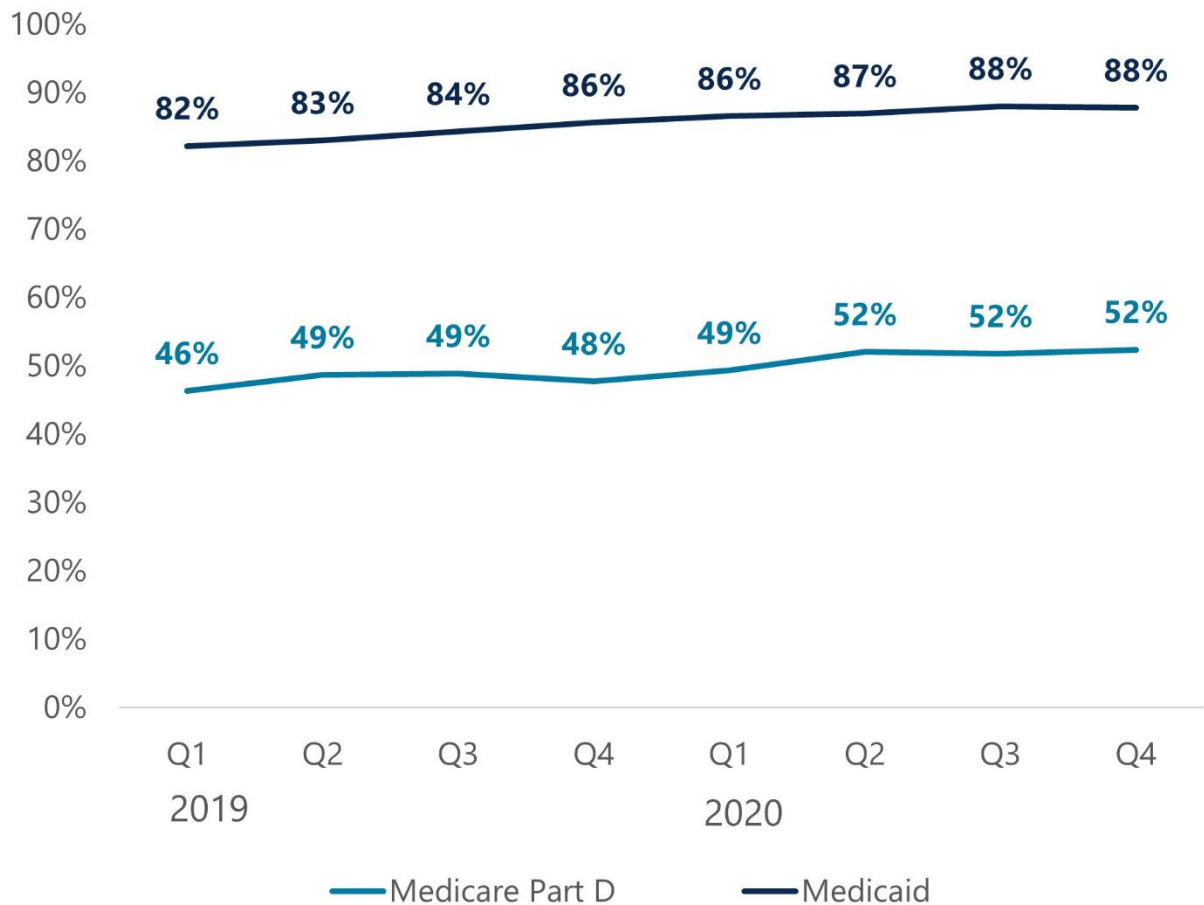
## Appendix A: 2020 Medicare Part D and beneficiary drug cost responsibility by coverage phase for beneficiaries who qualify for the LIS

Low-Income Subsidy (LIS)-Eligible Beneficiaries				
Coverage Phase	Full-Subsidy Eligible		Partial-Subsidy Eligible	
	Paid by Part D*	Paid by Enrollee	Paid by Part D*	Paid by Enrollee
<b>Deductible</b>	\$435	\$0	\$346	\$89
<b>Initial Coverage</b>	100% less enrollee cost-sharing	\$0-\$8.95	85%	15%
<b>Coverage Gap</b>	100% less enrollee cost-sharing	\$0-\$8.95	85%	15%
<b>Catastrophic Coverage</b>	100%	\$0	100% less enrollee cost-sharing	\$3.60-\$8.95

Source: 42 CFR § 423.782 and OIG analysis of data from CMS, "Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter."

\*Note: This total includes plan drug cost responsibility and the LIS.

## Appendix B: Utilization trends of beneficiaries who initiated treatment with a lower-cost hepatitis C drug in Medicare Part D and Medicaid, 2019-2020



Source: OIG analysis of 2020 Medicare Part D PDE records and T-MSIS data.

Note: The percentage of beneficiaries who initiated treatment with a lower-cost hepatitis C drug in Medicare and Medicaid presented in this Appendix may differ from the sum of the two lower-cost drug categories in Exhibit 5 due to rounding.

## Appendix C: Average 2020 beneficiary out-of-pocket costs for higher-cost versus lower-cost hepatitis C drugs among beneficiaries receiving varying levels of financial assistance

### Beneficiaries whose out-of-pocket costs were not reduced by financial assistance

	Number of beneficiaries	Average out-of-pocket costs
Taking higher-cost hepatitis C drugs	4,563	\$5,351
Taking lower-cost hepatitis C drugs	4,688	\$3,130

### Beneficiaries whose out-of-pocket costs were reduced by any form of financial assistance

Types of financial assistance in this category include the low-income subsidy (LIS), State pharmaceutical assistance programs, charities, group health plans, etc.

	Number of beneficiaries	Average out-of-pocket costs
Taking higher-cost hepatitis C drugs	13,189	\$75
Taking lower-cost hepatitis C drugs	12,525	\$50

### Beneficiaries whose out-of-pocket costs were reduced by the LIS only

We examined this category of beneficiaries in addition to the above category, as the LIS was the primary form of financial assistance received by Medicare beneficiaries who were treated for hepatitis C in 2020.

	Number of beneficiaries	Average out-of-pocket costs
Taking higher-cost hepatitis C drugs	12,099	\$40
Taking lower-cost hepatitis C drugs	11,657	\$28

Source: OIG analysis of 2020 Medicare Part D PDE records.

## Appendix D: Agency Comments

Following this page are the official comments from CMS.





Administrator

Washington, DC 20201

**DATE:** August 4, 2022

**TO:** Suzanne Murrin  
Deputy Inspector General for Evaluation and Inspections  
Office of Inspector General

**FROM:** Chiquita Brooks-LaSure *Chiq B LaS*  
Administrator  
Centers for Medicare & Medicaid Services

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending*, OEI-BL-21-00200

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to ensuring that Medicare beneficiaries have access to high quality and affordable health care while, at the same time, working to preserve the Medicare Trust Funds. Recognizing that Medicare payment policy can play a large role in promoting use of more affordable drugs, CMS is committed to continuing to promote competition, support increased utilization of generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries, within the authorities granted under statute.

OIG found that since the release of authorized generic versions of two hepatitis C drugs in January 2019, there has been an increase in both Medicare and Medicaid patients receiving the lower-cost versions, though Medicare uptake was lower than Medicaid. In the Medicare Part D program, Medicare contracts with private plan sponsors to provide a prescription drug benefit. A provision in the law that established the Medicare Part D program specifically prohibits the Secretary of the Department of Health & Human Services from requiring a particular formulary of covered Part D drugs. CMS exercises its authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries.

It is important to note that factors outside of coverage and payment policy may affect provider and beneficiary preferences for a reference product versus the authorized generic, as well as inclusion on plan formularies. For example, prescribers or beneficiaries may prefer the more familiar reference product when an authorized generic first enters the market. In addition, after the authorized generic has been on the market for some time, the price of an authorized generic may fall below the cost of the reference product even when taking the reference product's rebate into consideration, which may drive uptake and increased market share for the authorized generic. Using the biosimilars market as an example, the earliest biosimilar, Zarxio, which came onto the market in 2015 is now represented on over 80 percent of Medicare Part D plan formularies and has a significantly greater market share than its reference product.

CMS is committed to continuing to work within its authority to address both cost and access concerns. OIG's recommendations and CMS' responses are below.

**OIG Recommendation**

CMS should encourage Part D plans to increase access to and the use of the authorized generic versions of Epclusa and Harvoni, within the authorities granted under statute.

**CMS Response**

CMS concurs with OIG's recommendation. Within our authority, CMS is committed to taking action, as appropriate, to increase access to and use of lower-cost products, including authorized generic drugs.

OIG recommended that CMS could develop a voluntary innovation model through its Center for Medicare and Medicaid Innovation. While a multitude of policy and operational considerations influence whether CMS implements a model, CMS intends to examine how models could be used to test methods to lower beneficiary and program spending on drugs and incentivize the use of authorized generic drugs. CMS will continue to explore options to address this issue.

OIG also recommended that CMS could monitor Part D plans' submitted formularies to examine coverage trends of the relatively new authorized generic versions of Hepatitis C drugs, Epclusa and Harvoni. Specifically, CMS could consider determining whether formulary coverage of the authorized generic versions increases as they become more entrenched in the hepatitis C treatment market and consider identifying formularies that continue to include the brand-name versions while excluding the authorized generic versions. As discussed above, CMS' authority to review Part D plan formularies centers on ensuring that plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. Authorized generic drugs are the same as brand-name drugs, other than the fact that the brand-name is not on the label. Thus, while CMS is aware of coverage trends of these medications through review of plans' formularies, monitoring whether or not these drugs are included on formularies where the brand-name drug is also included would not have an effect on access to medically necessary treatments, nor allow CMS to take action within the authorities granted under statute.

**OIG Recommendation**

CMS should pursue additional strategies—such as educating providers and pharmacies—to increase access to and use of lower-cost hepatitis C drugs in Medicare Part D.

**CMS Response**

CMS concurs with OIG's recommendation. CMS will look to pursue additional strategies to increase access to and use of lower-cost drugs, including hepatitis C authorized generic drugs, in Medicare Part D.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

# ACKNOWLEDGMENTS AND CONTACT

## Acknowledgments

Michael Kvassay served as the team leader for this study, and Kasey Memphis served as the lead analyst. Others in the Office of Evaluation and Inspections who conducted the study include Bahar Adili. Office of Evaluation and Inspections headquarters staff who provided support include Althea Hosein, Christine Moritz, Michael Novello, and Sarah Swisher.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Amber Jessup and Jessica Swanstrom.

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office, Heather Barton, Deputy Regional Inspector General, and Louise Schoggen, Assistant Regional Inspector General.

## Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov). OIG reports and other information can be found on the OIG website at [oig.hhs.gov](http://oig.hhs.gov).

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# ENDNOTES

<sup>1</sup> Office of Inspector General (OIG) analysis of Medicare Part D drug spending for direct-acting antivirals used to treat chronic hepatitis C infections.

<sup>2</sup> Although hepatitis C is a short-term illness for some people, most people infected with the hepatitis C virus develop a long-term, chronic infection. The hepatitis C drugs discussed in this report are approved to treat chronic hepatitis C. Centers for Disease Control and Prevention (CDC), Hepatitis C Information, July 28, 2020. Accessed at <https://www.cdc.gov/hepatitis/hcv/index.htm> on February 10, 2021.

<sup>3</sup> Before direct-acting antivirals, hepatitis C was treated for decades with painful shots of interferon and a pill called ribavirin. These treatments were associated with only a 50-percent cure rate. Treatment lasted 48 weeks and had adverse and often intolerable side effects. Harvoni was the first all oral hepatitis C treatment approved by the U.S. Food and Drug Administration (FDA). WebMD, "Hepatitis C Treatments," October 25, 2021. Accessed at <https://www.webmd.com/hepatitis/understanding-hepatitis-c-treatment> on March 15, 2022. Pollack, A., "Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval," October 10, 2014, *New York Times*. Accessed at <https://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html> on April 5, 2021.

<sup>4</sup> A manufacturer's list price (sometimes referred to as the wholesale acquisition cost) for a drug or biological does not include prompt pay or other discounts, rebates, or reductions in price.

<sup>5</sup> Kalidindi, Y., et al., "Association of Direct-Acting Antiviral Treatment With Mortality Among Medicare Beneficiaries With Hepatitis C," *JAMA Network Open* Volume 3, Number 7, July 2020.

<sup>6</sup> Silverman, E., "FDA Approves a Gilead pill that is first to treat all forms of hepatitis C," June 28, 2016, *STAT*. Accessed at <https://www.statnews.com/pharmalot/2016/06/28/fda-approves-gilead-hepatitis-c/> on March 17, 2022.

<sup>7</sup> Gilead Sciences, Inc., "A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV," Company Statement, September 24, 2018. Accessed at <https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv> on March 16, 2022.

<sup>8</sup> By identical, we mean that—other than the fact that an authorized generic does not have the brand name on its label—an authorized generic version of a drug is the exact same drug product as the brand-name drug, according to FDA. However, authorized generic versions of a tablet or capsule may not be identical in appearance to the brand-name version (e.g., a different color or marking). FDA, "FDA List of Authorized Generic Drugs." Accessed at <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs> on August 8, 2022.

<sup>9</sup> IQVIA US Market Access Strategy Consulting analysis found that commercial payers and Medicaid quickly shifted away from the brand-name versions of Harvoni and Epclusa to their significantly cheaper authorized generic versions, or to another cheaper hepatitis C drug called Mavyret. Fein, A., "Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors," January 22, 2020, *Drug Channels Blog*. Accessed at <https://www.drugchannels.net/2020/01/why-part-d-plans-prefer-high-list-price.html> on July 7, 2021.

<sup>10</sup> Section 101, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173; Social Security Act § 1860D-1(a).

<sup>11</sup> Part D sponsors can offer prescription drug coverage under stand-alone prescription drug plans (PDPs) and/or Medicare Advantage prescription drug plans (MA-PDs). Social Security Act § 1860D-1(a).

<sup>12</sup> Congressional Research Service (CRS), "Medicare Part D Prescription Drug Benefit," December 2020.

<sup>13</sup> Social Security Act § 1860D-11(i)(1).

<sup>14</sup> Social Security Act § 1860D-2.

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<sup>15</sup> 42 CFR § 423.4.

<sup>16</sup> Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a nonpreferred drug on the plan's formulary. 42 CFR § 423.100. In addition to formulary inclusion/placement, plans rely on other utilization management tools, such as prior authorization requirements and step therapy, to limit use of certain drugs.

<sup>17</sup> Social Security Act § 1860D-11(i)(2).

<sup>18</sup> Social Security Act § 1860D-11(e)(2)(D)(i), 42 CFR § 423.120(b)(2), and Chapter 6, Section 30.2.7, of the Medicare Prescription Drug Benefit Manual.

<sup>19</sup> 42 CFR § 423.104(c)-(e).

<sup>20</sup> 42 CFR § 423.2325. Brand-name and authorized generic drug costs are offset in the coverage gap by the 70 percent discount manufacturers are required to provide for non-LIS beneficiaries in the coverage gap.

<sup>21</sup> Copayments are fixed payment amounts made by a beneficiary for a drug. Coinsurance payments are generally based on a percentage of the drug's cost. Premium costs are not included in out-of-pocket costs.

<sup>22</sup> CRS, "Medicare Part D Prescription Drug Benefit," op cit.

<sup>23</sup> CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)," Fact Sheet, January 19, 2017. Accessed at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> on November 30, 2021.

<sup>24</sup> Out-of-pocket spending is capped for beneficiaries receiving the full LIS. CRS, "Medicare Part D Prescription Drug Benefit," op. cit.

<sup>25</sup> 42 CFR § 423.773(a)-(b). Part D beneficiaries who are eligible for Medicaid are automatically eligible for the LIS regardless of income level. 42 CFR § 423.773(c)(1).

<sup>26</sup> CRS, "Medicare Part D Prescription Drug Benefit," op cit.

<sup>27</sup> Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, "Chapter 14: The Medicare prescription drug program (Part D): Status report," March 2020.

<sup>28</sup> OIG analysis of 2020 Part D prescription drug event data.

<sup>29</sup> In 2021, approximately 1 in 4 Medicare Part D enrollees received assistance through the LIS program. Cubanski, J., et al., "Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021," June 8, 2021, Kaiser Family Foundation. Accessed at <https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/> on March 16, 2022.

<sup>30</sup> Medicare also makes low-income cost-sharing subsidy payments and risk-sharing payments.

<sup>31</sup> See Social Security Act § 1860D-15(a)(1) for directy subsidy calculation details.

<sup>32</sup> 42 CFR § 423.329(c)

<sup>33</sup> CRS, "Medicare Part D Prescription Drug Benefit," op cit.

<sup>34</sup> 42 CFR § 423.343

<sup>35</sup> 42 CFR § 423.308

<sup>36</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, "Chapter 5: Realigning incentives in Medicare Part D," June 2020.

<sup>37</sup> CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)," op cit.

<sup>38</sup> United States Government Accountability Office (GAO), *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*, GAO-19-498, July 2019.



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- <sup>39</sup> Part D plan sponsors must factor expected DIR—including rebates—for the upcoming payment year into their plan bids which are used by CMS to calculate premiums. In other words, projected DIR reduces sponsors' estimated costs to provide the Part D benefit, which in turn reduces premiums.
- <sup>40</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, "Chapter 5: Realigning incentives in Medicare Part D," op. cit.
- <sup>41</sup> Lieberman, S., et al., "Sharing Drug Rebates With Medicare Part D Patients: Why And How," September 14, 2020, *Health Affairs Forefront*. Accessed at <https://www.healthaffairs.org/doi/10.1377/hblog20200911.841771/full/> on March 16, 2022.
- <sup>42</sup> CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)," op cit.
- <sup>43</sup> Congressional Budget Office (CBO), "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029," May 2019.
- <sup>44</sup> CMS, "Proposed Safe Harbor Regulation Impact," August 3, 2018. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf> on December 2, 2021.
- <sup>45</sup> Pollack, A., "Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval," op cit.
- <sup>46</sup> Shye, R., "New Hepatitis C Med Eplusa Now Approved," July 28, 2016, GoodRx Health. Accessed at <https://www.goodrx.com/blog/new-hepatitis-c-med-eplusa-now-approved/> on April 4, 2021.
- <sup>47</sup> Andrews, M., "FDA's Approval Of A Cheaper Drug For Hepatitis C Will Likely Expand Treatment," October 4, 2017, NPR. Accessed at <https://www.npr.org/sections/health-shots/2017/10/04/555156577/fdas-approval-of-a-cheaper-drug-for-hepatitis-c-will-likely-expand-treatment> on March 16, 2022.
- <sup>48</sup> Gilead Sciences, Inc., "A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV," op cit.
- <sup>49</sup> The nonproprietary name of the Eplusa authorized generic is sofosbuvir/velpatasvir and the nonproprietary name of the Harvoni authorized generic is ledipasvir/sofosbuvir.
- <sup>50</sup> Different hepatitis C drugs are FDA-approved to treat different hepatitis C virus genotypes. For example, Harvoni and its authorized generic are approved to treat only select genotypes whereas Eplusa, its authorized generic, and Mavyret are approved to treat all six basic hepatitis C genotypes.
- <sup>51</sup> FDA, "FDA List of Authorized Generic Drugs," op cit.
- <sup>52</sup> Social, M., et al., "Factors Associated With Prescriptions for Branded Medications in the Medicare Part D Program," *JAMA Network Open* Volume 4, Number 3, March 2021.
- <sup>53</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, "Chapter 5: Realigning incentives in Medicare Part D," op. cit.
- <sup>54</sup> Lieberman, S., et al., "Sharing Drug Rebates With Medicare Part D Patients: Why And How," op. cit.
- <sup>55</sup> 82 FR 56336, 56421 (November 28, 2017).
- <sup>56</sup> Fein, A., "Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors," op cit.
- <sup>57</sup> For brand-name drugs, rebates in Medicaid are sometimes tied to a drug's "best price," i.e., the lowest price paid for a drug by any purchaser in the United States, with exceptions. Notably, Part D prices are not considered in the Medicaid best price calculation, which may influence manufacturers to offer higher rebates to Part D sponsors than commercial payers.
- <sup>58</sup> Dolan, R., "Understanding the Medicaid Prescription Drug Rebate Program," November 12, 2019, Kaiser Family Foundation. Accessed at <https://www.kff.org/medicaid/issue-brief/understanding-the-medicicaid-prescription-drug-rebate-program/> on March 1, 2022.
- <sup>59</sup> State Medicaid programs regularly publish updated Preferred Drug Lists on their websites. Examples of States that list lower-cost hepatitis C drugs such as Mavyret or the authorized generic version of Eplusa as a preferred direct-acting antiviral treatment for hepatitis C as of May 5, 2022, include the following: Florida, West Virginia, Ohio, Georgia, Missouri, and Arkansas. Note that this list is not exhaustive.



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- <sup>60</sup> Courses of treatment among hepatitis C drugs range from 8 to 24 weeks. We used the most common length of treatment—12 weeks—to compare list prices among all the hepatitis C drugs in our study, except Mavyret which has a typical treatment length of 8 weeks.
- <sup>61</sup> Gilead Sciences, Inc., “A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV,” op cit.
- <sup>62</sup> MedPAC, *Report to the Congress: Medicare Payment Policy*, “Chapter 13: The Medicare prescription drug program (Part D): Status report,” March 2021.
- <sup>63</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, “Chapter 5: Realigning incentives in Medicare Part D,” op. cit.
- <sup>64</sup> Lieberman, S., et al., “Sharing Drug Rebates With Medicare Part D Patients: Why And How,” op. cit.
- <sup>65</sup> Sacks, C., et al., “Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions,” August 31, 2020, *JAMA Internal Medicine* Volume 181, Number 1, August 2020.
- <sup>66</sup> National Conference of State Legislators, “Generic Drug Substitution Laws,” May 3, 2019. Accessed at [https://www.ncsl.org/portals/1/documents/health/Generic\\_Drug\\_Substitution\\_Laws\\_32193.pdf](https://www.ncsl.org/portals/1/documents/health/Generic_Drug_Substitution_Laws_32193.pdf) on January 21, 2022.
- <sup>67</sup> Liu, A., “Gilead’s stealing hep C share with its cut-rate Eplusa and Harvoni generics,” September 16, 2019, *Fierce Pharma*. Accessed at <https://www.fiercepharma.com/pharma/gilead-s-authorized-hcv-generics-now-own-over-20-market> on April 25, 2022.
- <sup>68</sup> AbbVie, Inc., “Common Questions about Mavyret.” Accessed at <https://www.mavyret.com/frequently-asked-questions> on April 25, 2022. AbbVie defines cure as no hepatitis C virus found in the blood 3 months after treatment ends. Mavyret is used to treat adults and children 3 years of age and older with chronic hepatitis C virus genotypes 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; or GT 1 infection in someone who has been previously treated with a regimen that contained a hepatitis C NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
- <sup>69</sup> Abutaleb, A., et al., “Glecaprevir/pibrentasvir expands reach while reducing cost and duration of hepatitis C virus therapy,” *Hepatology International* Volume 12, Number 3, May 2018.
- <sup>70</sup> For some beneficiaries, it may be medically necessary or more appropriate to receive a higher-cost hepatitis C drug rather than a lower-cost alternative, even if the drug is approved to treat the same genotype(s) of hepatitis C. For example, a patient may be allergic to ingredients in lower-cost drugs that are not in higher-cost drugs, or a patient may find a lower-cost drug’s adverse effects intolerable but not experience those effects with a higher-cost drug.
- <sup>71</sup> Grover, A. and Erlich, D.R., “New Drug Reviews: Glecaprevir/Pibrentasvir (Mavyret) for the Treatment of Chronic Hepatitis C,” *American Family Physician* Volume 98, Number 10, November 2018.
- <sup>72</sup> Abutaleb, A., et al., “Glecaprevir/pibrentasvir expands reach while reducing cost and duration of hepatitis C virus therapy,” op cit.
- <sup>73</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, “Chapter 5: Realigning incentives in Medicare Part D,” op. cit.
- <sup>74</sup> Lieberman, S., et al., “Sharing Drug Rebates With Medicare Part D Patients: Why And How,” op. cit.
- <sup>75</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, “Chapter 5: Realigning incentives in Medicare Part D,” op. cit.
- <sup>76</sup> Ninety-seven percent of Part D beneficiaries taking higher-cost hepatitis C drugs reached catastrophic coverage in 2020, and ninety-five percent of Part D beneficiaries taking lower-cost hepatitis C drugs reached catastrophic coverage.
- <sup>77</sup> Social Security Act § 1860D-15(b). The final plan payments (reinsurance) by CMS are, per statute, to be based on the costs actually incurred by Part D sponsors and must reflect any applicable DIR. DIR is apportioned only between Medicare and the Part D plan, generally based on the share of the total Part D drug costs that each is responsible for over the course of the payment year. CMS, “Medicare Part D – Direct and Indirect Remuneration (DIR),” op cit.

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<sup>78</sup> MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, "Chapter 5: Realigning incentives in Medicare Part D," op cit.

<sup>79</sup> Martin, K., "Essential Facts About Drug Pricing Reform: Medicare Part D Redesign," May 5, 2021, The Commonwealth Fund. Accessed at <https://www.commonwealthfund.org/publications/explainer/2021/may/medicare-part-d-redesign> on March 16, 2022.

<sup>80</sup> Some beneficiaries may have a medical need for taking higher-cost hepatitis C drugs instead of lower-cost alternatives.

<sup>81</sup> CMS, "Part D Payment Modernization Model." Accessed at <https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model> on March 1, 2022.