

# AUDITING THE PRESCRIPTION DRUG CONSUMER PRICE INDEX IN A CHANGING MARKETPLACE

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## I. INTRODUCTION AND BACKGROUND

Prescription drug spending and drug prices are central to concerns about rapidly rising health spending. A variety of legislative proposals have been advanced aimed at reining in drug prices and drug price growth. The debate around these proposals is rancorous and frequently focuses on differing perceptions of how rapidly drug prices are growing.

One key source of information is the Department of Labor, Bureau of Labor Statistics' (BLS') Consumer Price Index (CPI), which includes a component that measures growth in prescription drug prices. The prescription drug component of the CPI has real world impacts as it is used to construct payment updates by insurers and regulators, is often a consideration in contract negotiations within the health care industry and is used to estimate trends in National Health Expenditures and its components.

But there are reasons to suspect that the CPI has not been a good measure of actual trends in prescription drug prices. Most importantly, the CPI almost surely misses a large share of specialty medicines. Specialty drugs, such as those that treat cancers and immune system disorders, carry high prices, have experienced high rates of price and spending growth, and have claimed a rapidly growing share of drug spending, reaching 55% of U.S. drug spending in 2021, nearly double the 28% share from ten years prior.<sup>1</sup>

In the analysis that follows, we assess how the treatment of specialty drugs in the CPI affects growth in measured prescription drug prices. We conduct this assessment using data from large insured populations covered by employer-sponsored health insurance. While this is not a fully comprehensive analysis of all purchases of prescription drugs, it offers informative insights into how data on prescription drug prices are collected and used to understand prescription drug price changes. We note that the analysis is geared towards the approaches

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<sup>1</sup> IQVIA Institute for Human Data Science [2022], pp. 2-3.

used to calculate the prescription drug CPI. We do not take up issues related to accounting for product quality in this analysis.

The results demonstrate that considerable caution should be taken in interpreting the prescription drug component of the CPI as a comprehensive reflection of price growth in those markets. This is because the shift to specialty drugs involves dispensing by specialty pharmacies, hospitals, and physician offices – sites that are frequently not included as part of the prescription drug CPI that is confined to surveys of retail outlets. Instead, drug prices have increasingly become a component of the price indexes for hospitals, physician offices, and other health care settings.

The remainder of this manuscript is organized into three additional sections. Section II provides a detailed analysis of the role of the prescription drug CPI (“CPI-Rx”) in the larger construction of the nation’s CPI. That section also offers a detailed description of how the prescription drug CPI is constructed including the approach to data collection and the weighting schemes used to aggregate a complex set of products. Section II also provides detailed evidence on how different types of prescription drug products are incorporated into the various component indexes. That evidence offers the basis for a hypothesis about potential distortions in the existing CPI-Rx. Section III describes and conducts an empirical analysis that compares the application of the current CPI methodology to one that more completely (but still not entirely) takes account of the evolution of prescription drug markets. Finally, section IV summarizes the results and considers implications of the findings for ongoing policy debates and our understanding of prescription drug price behavior.

## II. THE BLS' CPI MEDICAL CARE HIERARCHICAL PROGRAM STRUCTURE

### A. OVERVIEW AND RECENT COMPOSITIONAL CHANGES

The CPI has a hierarchical structure. Table 1 below displays the hierarchy of the medical care (MC) major group, and relative importance of the various components of MC as of December 2010 and about a decade later, in December 2021 (several of the detailed items are not available for 2010). A few salient facts emerge from Table 1.

**Table 1. Structure of Medical Care Group in Medical Care CPI, and Relative Importance, 2010 and 2021**

CPI Medical  <u>Care Item</u>	Relative Importance (%)		Percentage of Total MC	
	<u>2010</u>	<u>2021</u>	<u>2010</u>	<u>2021</u>
<b>Medical Care</b>	6.627	8.487	100%	100%
<b>Medical Care Commodities</b>	1.633	1.524	25%	18%
<b>Medicinal Drugs</b>		1.422		17%
<b>Prescription Drugs</b>		1.044		12%
<b>Non-Prescription Drugs</b>		0.378		4%
<b>Medical Equipment &amp; Supplies</b>		0.103		1%
<b>Medical Care Services</b>	4.994	6.962	75%	82%
<b>Professional Services</b>	2.830	3.585	43%	42%
<b>Physicians' Services</b>		1.900		22%
<b>Dental Services</b>		0.924		11%
<b>Eyeglasses &amp; Eye Care</b>		0.371		4%
<b>Services—Other Med</b>		0.390		5%
<b>Professionals</b>				
<b>Hospital &amp; Related Services</b>	1.703	2.573	26%	30%
<b>Hospital Services</b>		2.199		26%
<b>Inpatient Hospital</b>		N/A		N/A
<b>Services*</b>				
<b>Outpatient Hospital</b>		N/A		N/A
<b>Services*</b>				
<b>Nursing Home &amp; Adult Day</b>		0.210		
<b>Care Services</b>				
<b>Elderly at home</b>		0.164		2%
<b>Health Insurance</b>	0.461	0.804	7%	9%

\*Substratum index: A special index published below typical item level. The relative importance weight is not available for these indexes. Source: U.S. Bureau of Labor Statistics [2022a], Table A, pp. 1-2/7; U.S. Bureau of Labor Statistics [2011a], Table 1. Note: Several of the detailed CPI medical care items are not available for 2010 in the BLS' [2011a] publication.

The first fact to note is that medical care (MC) costs as a share of total consumer expenditures have risen in the eleven years between December 2010 and December 2021. The total MC relative importance was 6.627 percent in 2010, and by December 2021 it increased to 8.487 percent – an increase of 1.86 percentage points, or a proportional increase of 28.1% ( $1.86/6.627$ ).<sup>2</sup>

As background to our second major observation in Table 1, we note there are eight major group categories in the top tier of the CPI – food, housing, apparel, transportation, medical care, recreation, education and communication, and other goods and services. In the second tier of the MC CPI hierarchy, the eight major groups are divided into 70 expenditure classes. The medical care (MC) group is divided into two main components: medical care services (MCS) and medical care commodities (MCC), each containing several item categories. This brings us to the second salient observation concerning recent changes in MC. Within total MC, between 2010 and 2021 there has been a shift toward medical care services (MCS) and away from medical care commodities (MCC). MCS is the largest item component, in 2010 representing about 75% of the weight within MC<sup>3</sup>, increasing to 82% in 2021.<sup>4</sup> MCC made up approximately 25% of the weight within MC in 2010,<sup>5</sup> but decreased to 18% by 2021.<sup>6</sup>

Our third key observation involves the role of prescription pharmaceuticals within total MC in the U.S. Within the MCC component, prescription pharmaceutical drugs constitute the bulk of the MCC total weight. In 2010, prescription pharmaceuticals accounted for roughly 75% of the

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<sup>2</sup> U. S. Bureau of Labor Statistics, [2011a], Table 1. U. S. Bureau of Labor Statistics [2022a], Table A.

<sup>3</sup> According to U.S. Bureau of Labor Statistics [2011a], Table 1, as of December 2010, the relative importance of medical care services in total medical care was  $4.994/6.627 = 0.75358$ .

<sup>4</sup> U. S. Bureau of Labor Statistics [2022a], Table A.

<sup>5</sup> In U.S. Bureau of Labor Statistics [2011a], Table 1, the relative importance of medical care commodities in total medical care was  $1.633/6.627 = 0.2464$ .

<sup>6</sup> In U.S. Bureau of Labor Statistics [2022a], Table A, pp. 1-2/7, the medical care services share is 82% of medical care ( $6,692/8.487$ ), while that for medical care commodities is 18% ( $1.524/8.487$ ).

total expenditure for MCC,<sup>7</sup> but as seen in Table 1, in 2021 the prescription pharmaceutical weight fell to only 68%.<sup>8</sup> An important implication is that while in 2010 prescription pharmaceuticals accounted for about 19% of total MC expenditures ( $\approx 75\% \times 25\%$ ), by 2021 the prescription drug share in total MC expenditures fell substantially to about 12% ( $\approx 68\% \times 18\%$ ).<sup>9</sup>

Although prescription pharmaceuticals brought about a major compositional change within MCC and within total MC between 2010 and 2021, considerably smaller compositional changes have occurred within MCS. As of December 2010, Professional Services accounted for 42.7% of the total MC relative importance weight ( $= 2.830/6.627$ ).<sup>10</sup> As of December 2021, as reported in the March 2022 CPI, the Professional Services weight in total MC was essentially unchanged at 42.2% ( $= 3.585/8.487$ ).<sup>11</sup> Hospital and related services increased slightly in relative importance between 2010 and 2021, accounting for 25.7% ( $= 1.703/6.627$ ) of the total MC weight in 2010,<sup>12</sup> but by 2021 this weight increased to 30.3% ( $= 2.573/8.487$ ).<sup>13</sup> Finally, the health insurance services component of MCS was 6.94% ( $= 0.461/6.627$ ) of the total MC relative importance weight in 2010, but by 2021 this weight increased by about two percentage points to 9.5% ( $0.804/8.487$ ).<sup>14</sup> In summary, the medical care marketplace has changed considerably in the eleven years between 2010 and 2021. The largest absolute percentage

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<sup>7</sup> U.S. Bureau of Labor Statistics [2011b], p. 6.

<sup>8</sup> In U.S. Bureau of Labor Statistics [2022a], Table A, p. 1/7, the relative importance of prescription drugs in medical care commodities is  $1.044/1.524 = 0.6850$ .

<sup>9</sup> In U.S. Bureau of Labor Statistics [2022a], pp. 1-2/7, prescription drugs account for about two-thirds of the medical care commodities weight (12% of 18%), non-prescription drugs account for 4%, and medical equipment and supplies (including non-prescription medicines and dressings used externally, contraceptives, and supportive and convalescent medical equipment, e.g., adhesive strips, heating pads, athletic supporters, and wheelchairs. Using the updated U.S. Bureau of Labor Statistics [2022a] numbers, this prescription drug share falls to about 12% ( $68\% \times 18\%$ ).

<sup>10</sup> U.S. Bureau of Labor Statistics [2011a], Table 1.

<sup>11</sup> U.S. Bureau of Labor Statistics [2022a], Table A.

<sup>12</sup> U.S. Bureau of Labor Statistics [2011a], Table 1.

<sup>13</sup> U.S. Bureau of Labor Statistics [2022a], Table A.

<sup>14</sup> Note that the sum of these three relative importance weights within MCS as a share of total MC costs was 0.7536 in 2010, but increased to 0.8203 in 2021, an increase of about 6.67 percentage points.

points compositional changes within the BLS' MC CPI involved the increase in MCS (from 75% to 82%), the decrease in MCC (from 25% to 18%), the decline in the prescription pharmaceuticals (from 19% to 12%), and the increase in hospital and related services (from 26% to 30%).

In interpreting these compositional changes in MC spending, we believe it important to recognize that the transactions prices recorded are the sum of all payments to a health care provider from all payers – cash, commercial insurers, Medicare Part B insurance, and Medicare Part D insurance. Thus, for example, when a retail pharmacy or a hospital receives payment for a dispensed prescription or a delivered hospital service, the transaction expenditure payment recorded in the BLS' CPI is, in the case of a prescription, the patient's out-of-pocket copayment or coinsurance payment to the retail pharmacy plus the reimbursement to the pharmacy by the insurer; in the case of a hospital service, the CPI transaction expenditure recorded is the cash out-of-pocket payment by the patient plus the amount reimbursed the hospital by the insurer. Note that any payments from Medicaid or worker's compensation program to the provider (e.g., to a pharmacy or hospital) are not included in the CPI, because unlike Medicare Part B or Medicare Part D, there are typically no insurance premiums required to obtain coverage as a Medicaid or a worker's compensation beneficiary. In contrast, Medicare beneficiaries are generally required to make regular premium payments.<sup>15</sup> In the process of aggregating specific transactions items into medical care components and major groups, each item index in Table 1 is assigned a weight. The weight of each item in the CPI is determined using the Consumer Expenditure Survey (CES), which collects information from the nation's households and families on their buying habits or expenditures, income, and household characteristics every two

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<sup>15</sup> U. S. Bureau of Labor Statistics [2011b], p., 6. Also see U.S. Bureau of Labor Statistics [2022a], p. 1/7. Note this logic implies that the free COVID-19 vaccinations provided by the U.S. federal government are not tracked by the medical care CPI. That might change if the federal government terminates its support for free COVID vaccinations.

years.<sup>16</sup> Goods and services that consumers spend the most on will be the most heavily weighted. The CES tracks consumer out-of-pocket spending on medical care, which is used to weight the medical care indexes. The CES defines out-of-pocket medical spending as the sum of three payments: (i) patient payments made directly to retail establishments for medical goods and services; plus (ii) health insurance premiums paid for by the consumer, including Medicare Part B; plus (iii) health insurance premiums deducted from employee paychecks. Note that employer paid portions of insurance premiums and fully tax-funded medical care (such as the expenses paid by Medicare Part A and Medicaid) are not considered out-of-pocket, and therefore are not used in weighting the indexes.<sup>17</sup> The weight used in the CPI MC represents the sum of payments from cash and insurance sources.

## II.B. ALLOCATION AMBIGUITIES IN THE MEDICAL CARE CPI

The MC CPI allocates the total payments made in a transaction to one and only one of the MC components. This creates ambiguities. Consider when during a hospital stay a patient has a pacemaker installed – a medical equipment item. Is this considered a hospital and related services expenditure in the CPI, or a medical equipment and supplies expenditure? And what if the cardiologist implanting the device bills the hospital for the procedure – is that a hospital and related services expenditure, or a physician service within the professional services category of MC? Or consider an oncologist who has infusion chairs in her office where chemotherapy drugs are administered. Are the chemotherapy drug payments to the oncologist allocated to prescription pharmaceuticals within the BLS CPI MC accounting system, or are they assigned to physicians' professional services? If in the former case, the pacemaker bill is treated as part of hospital and related services, and if in the latter case the chemotherapy administration is treated as part of physicians' professional services, then the payment amounts underlying the BLS' CPI

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<sup>16</sup> U. S. Bureau of Labor Statistics [2019].

<sup>17</sup> U.S. Bureau of Labor Statistics [2022a], p. 1/7.



MC and its relative importance weights would likely understate the importance of pacemakers, or of chemotherapy, in affecting overall medical care costs. And if changes in the medical care marketplace affect the locations and offices where cardiac devices are implanted and where medicines are administered, then comparisons of medical care prices in the medical care CPI over time could be greatly affected by changes in the practice of medicine, even when none of the prices or payments for the underlying items and services change. This raises important issues of how one interprets the decrease in the prescription pharmaceutical weight in the BLS' CPI MC weight between 2010 and 2021, and the 2010-2021 increase in the hospital and related services weight. More generally, how does the BLS medical care CPI program account for activities that simultaneously involve different medical services and inputs?

In a 2011 U.S. Bureau of Labor Statistics publication describing pharmaceutical industry coverage in its Consumer Price Index (CPI), Producer Price Index (PPI), and Import/Export Price Index (IPP) programs, the BLS explicitly states "The CPI collects transactions prices received by the retail pharmacy."<sup>18</sup> Retail pharmacy includes brick and mortar retail, mail order, and internet, but excludes nursing home institutional care facilities, such as long term care facilities.<sup>19</sup> An accompanying table comparing the coverage and scope of the CPI, PPI and IPP programs describes the type of price collected by BLS as "Transaction price received by the pharmacy", and the coverage/scope as "Physician-prescribed prescription and non-prescription drugs dispensed via U.S. pharmacies (excludes physician and hospital administered drugs)."<sup>20</sup> Furthermore, the BLS explains: *"Prescription drugs that are administered in a hospital setting and billed by the hospital as a component part of a larger service will not be priced in the CPI*

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<sup>18</sup> U.S. Bureau of Labor Statistics [2011b], p. 6. Notably, this document does not discuss whether specialty pharmacies are included within the domain of retail pharmacies – we consider specialty pharmacies later in this manuscript.

<sup>19</sup> U.S. Bureau of Labor Statistics [2022a], pp. 1-2/7

<sup>20</sup> U.S. Bureau of Labor Statistics [2011b], Table 1, p. 2. In discussions with BLS personnel, we were informed that the CPI coverage also includes prescriptions dispensed in retail pharmacies that are written by non-physicians such as nurse practitioners and physician assistants who are authorized to prescribe drugs by state pharmacy boards.

*prescription drug index, such prices will instead be captured in the hospital index as part of a priced hospital service. (This is one area in which the PPI would pick up some drugs that the CPI would not, because the PPI ignores channel of distribution. Drugs that are used mostly in a hospital setting will be missing from the CPI sample.)”<sup>21</sup>*

Although the BLS document does not explicitly comment on coverage for nurse- and physician-administered drugs in physician offices or outpatient clinics, BLS officials have informed us the same logic applies, and such prescription transactions would be captured by the physicians’ services component within the physicians’ professional services item in MCS, not by the prescription drugs item in the MCC.

## II.C. WHOLESALERS, SPECIALTY DRUGS, AND SPECIALTY DISTRIBUTORS

Prescription drugs are shipped by manufacturers to wholesalers, and to a limited extent, to dispensing pharmacies. Wholesalers and specialty distributors then ship drugs to dispensing pharmacies, hospitals, and other medical care providers. In 2020, the three largest wholesalers were AmeriSource Bergen, Cardinal Health and McKesson, who together had a 96% market share.<sup>22</sup>

It is useful to distinguish full-line wholesalers from specialty distributors. Full-line wholesalers generally sell a manufacturer’s complete pharmaceutical product line to retail outpatient outlets (e.g., chain drug stores, independent pharmacies, mail pharmacies, mass merchandisers with pharmacies, and supermarkets with pharmacies), and institutional non-retail health care facilities such as long-term care pharmacies, hospitals, and physician offices/clinics. In 2019 retail outlets accounted for about 75% of full-line wholesaler revenues.<sup>23</sup>

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<sup>21</sup> U. S. Bureau of Labor Statistics [2011b], p. 7. Italics not in original source.

<sup>22</sup> Fein [2021], p. 25.

<sup>23</sup> Fein [2021], Exhibit 1, pp. 8-9.

Specialty distributors sell specialty pharmaceuticals (defined below) primarily to physician-owned/operated clinics, hospitals, and hospital-owned outpatient clinics. *Specialty pharmaceuticals* are distinguished from *traditional pharmaceuticals*. Several major specialty distributors are owned by the largest wholesalers (e.g., McKesson). In other cases, specialty distributors are free-standing distributors, a form of specialized wholesaler. Although there is no universal or legislated definition of specialty pharmaceuticals, they are typically identified as pharmaceuticals that treat chronic, complex illnesses such as cancer, rheumatoid arthritis, multiple sclerosis, and HIV; treat smaller patient populations and frequently require administration by a health care provider, such as a physician or nurse.<sup>24</sup> In recent years, specialty drugs accounted for slightly more than 2% of all U.S. outpatient prescriptions. In 2020, specialty drugs accounted for about 1/3 of full-line wholesalers' revenues, and for nearly all of specialty distributor revenues.<sup>25</sup> Specialty drugs are subject to a variety of special handling and prior authorization conditions. Moreover, limited distribution contracts are increasingly in place. These circumstances result in specialty drugs being largely dispensed by providers and

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**Table 2**

**2019 Specialty Distributor Sales by Therapeutic Area**

<b>Therapeutic Area</b>	<b>Sales (%)</b>
<b>Oncology (includes blood, breast, prostate and lung cancers)</b>	52%
<b>Inflammatory (including rheumatoid arthritis, Crohn's disease)</b>	9%
<b>Supportive Care (e.g., anemia, blood modifiers)</b>	7%
<b>Ophthalmology</b>	7%
<b>Hemophilia, bleeding disorders (includes renal diseases)</b>	6%
<b>Central nervous system (includes multiple sclerosis, Alzheimer's)</b>	4%
<b>Cardiovascular (includes pulmonary arterial hypertension)</b>	3%
<b>All others</b>	12%

Source: Fein [2021], Exhibit 5, p. 12

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<sup>24</sup> Fein [2021], p. 19.

<sup>25</sup> Fein [2021], p. 27.

specialty pharmacies. Given that the BLS restricts its pharmaceutical sampling frame to retail pharmacies, it is likely that few, if any, specialty pharmaceuticals are priced in the BLS' prescription pharmaceutical price index (but see "brown bagging" discussion below).

To highlight the different distribution channels for traditional and specialty drugs, Table 3 below provides the weighted average of specialty distributor sales by provider segment for 2019 and 2020. As seen there, two customer groups dominate – hospitals and independent physician-owned/operated clinics -- each purchase about 40% of specialty distributor sales, in both years. Specialty pharmacies are the third largest purchaser, at about 10%. It is very unlikely that specialty pharmacies are sampled and priced under the BLS' retail pharmacy category.

**Table 3**

**2019-20 Weighted Average Share of Specialty Distributor Sales by Customer Class**

<b><u>Provider Segment</u></b>	<b><u>2019</u></b>	<b><u>2020</u></b>
<b>Hospitals</b>	37.9%	39.7%
<b>Independent physician-owned/operated clinics</b>	40.5%	37.1%
<b>Specialty pharmacies &amp; mail order (regardless of parent company affiliation)</b>	8.8%	10.5%
<b>Government organizations</b>	3.3%	3.1%
<b>Retail Pharmacies</b>	2.7%	2.8%
<b>Other healthcare distributors</b>	1.7%	1.8%
<b>Hospital-owned/-operated clinics/specialty clinics</b>	1.4%	1.3%
<b>Long-term care facilities, nursing homes, etc.</b>	0.9%	0.9%
<b>Home health</b>	0.1%	0.0%
<b>Other</b>	2.8%	2.8%

Source: HDA Research Foundation, Specialty Pharmaceutical Distribution, Facts, Figures and Trends (2021 Edition), Figure 12, p. 14.

Notably, neither the hospital nor the physician-owned/operated clinics customer groups is likely to be captured in the CPI pharmaceutical product sample. Hospital sales of specialty drugs that amount to roughly 40% of specialty products are typically captured in the overall hospital component of the CPI and not in the CPI pharmaceutical component. Similarly, sales to

physician offices that account for about 37% to 40% of specialty products are frequently included in the physician and professional services component of the CPI, and not in the pharmaceutical CPI component. Only just under 3% of specialty pharmaceutical sales occur in the retail pharmacy channel, the channel monitored by the prescription pharmaceutical CPI.

In some cases, however, it is possible that the BLS pharmaceutical CPI program will capture sales and prices of specialty pharmaceuticals, depending in part on whether a particular transaction is a *white bag* or *brown bag* transaction. A white bag transaction occurs when a specialty pharmacy ships a patient prescription directly to the provider, such as a physician office or outpatient clinic. The provider stores the product (often in a dark and cold temperature environment) until the product is administered to the patient by the provider, who also bears inventory-holding costs. White bag transactions of specialty drugs are likely not captured by the BLS' prescription pharmaceutical product sample.

In contrast, in a brown bag transaction, the patient picks up a prescription at a brick-and-mortar retail pharmacy, or receives it via mail courier, stores it safely and properly at home and then takes the drug to the provider's office or outpatient clinic for administration by a physician or nurse. It is possible that brown bag transactions in retail pharmacies are captured in the BLS' prescription pharmaceutical program. A variant of the brown bag transaction described above involves a specialty pharmacy – not a traditional brick and mortar retail pharmacy – arranging for patient pickup, or the specialty pharmacy shipping the prescription to the patient via mail courier. In either the white bag or brown bag case, the specialty pharmacy receives payment from the third party-payer. For a few reasons (such as concerns that patients will not provide adequate, safe home storage), payers have sought to shift away from brown bagging over the last decade, but bagging remains a controversial procedure, and many physician office practices prefer traditional “buy and bill” to intermediation by specialty pharmacies.<sup>26</sup>

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<sup>26</sup> For further discussion of bagging and “buy and bill” procedures, see “The Provider-Administered Drug Market”, Section 3.1 in Fein [2021], pp. 68-81.

We now move to a discussion of how we estimate the extent to which physician- and hospital-administered drugs escape measurement by the BLS' prescription drug CPI and thus potentially provide inaccurate estimates of prescription drug price inflation. We begin with a discussion of data sources.

### III. DATA AND METHODS

#### A. DATA

The data for the assessment of the prescription drug CPI come from the IBM MarketScan™ Commercial Claims and Encounters Research Database for the years 2010-2019. These data include de-identified patient-specific medical inpatient and outpatient claims, outpatient pharmaceutical data (the source of our price information) and enrollment data for approximately 25-40 million people annually. The data come from a selection of approximately 350 payers consisting of large employers, health plans, and government and public organizations. The database does not include claims data from patients over age 65.

The data contain more than 100 million adjudicated mail-order or retail program prescription drug claims annually. The claims are final and include the total amount paid by all parties as well as out-of-pocket costs paid by the patient to satisfy any copayment, coinsurance, or deductible obligations. Generic and brand drugs are identified through national drug codes (NDCs) and a generic indicator flag contained in the data base.<sup>27</sup>

To identify specialty and non-specialty drugs in our sample we employ IQVIA's classification of specialty drugs.<sup>28</sup> In order for a molecule to be classified as a specialty product, the approved indication in the U.S. for the drug must be chronic, complex, rare, and/or genetic. If a drug passes the chronic/complex/rare/genetic criteria, it must also satisfy at least four of the following

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<sup>27</sup> IBM® RED BOOK™ and MarketScan® Research Databases.

<sup>28</sup> IQVIA Institute for Human Data Science [2019]

seven criteria: (a) have high annual cost, (b) initiated and maintained by a drug treatment specialist, (c) administered by a practitioner, (d) have special handling requirements (i.e., refrigeration or biohazard requirements), (e) require reimbursement assistance, (f) have limited distribution, and (g) require in-depth monitoring or extensive counseling. Using these criteria, IQVIA then groups molecules into four levels of specialty distribution: (a) 'Specialty', (b) 'Specialty inferred', (c) 'Specialty no info', and (d) 'non-specialty'. To qualify for the highest level of specialty distribution, 'Specialty', official documentation must exist that demonstrates the above criteria are met. If supporting documentation does not exist but it is highly likely that the molecule is a specialty drug, the product falls into the 'Specialty inferred' category. If no supporting documentation exists but it is reasonably likely that the molecule is a specialty drug, the molecule is classified as 'Specialty no info'. All other molecules are classified as 'non-specialty'. Most specialty drugs (99.9% of US drugs and 98.3% of global drugs) fall into the highest category of the specialty distribution. In accordance with IQVIA practice, we consider products that fall into any of the top three indicators to be specialty drugs.

Following the specialty identification process described above, IQVIA provided us with a list of 623 molecules designated as specialty or specialty inferred. The IQVIA specialty/specialty inferred list comprises 3.4% of all 18,324 drugs observed in MarketScan pharmacy claims in 2010-2019. This includes 5.5% of brand drugs and 2.8% of generic drugs in MarketScan. Although a small minority of total drug claims, specialty drugs on average represented 20% of pharmacy spending in MarketScan over the entire 2010-2019 time period, but this share grows over time, from 13% in 2010 to 22% in 2015 and 31% in 2019. About 29% of molecules in the IQVIA specialty list never appear in the MarketScan data over the 2010-2019 time period.

## B. METHODS

Our approach to gauging the mismeasurement in the CPI is to compute a price index for prescription drugs using the more comprehensive MarketScan data and compare it to the

published CPI. Because we are unsure of the share of specialty drugs captured in the official CPI, we compare a CPI that captures 100% of specialty drugs in MarketScan to alternative CPIs that capture 5%, 25%, 33%, and 50% of specialty drugs. This approach has three main limitations. First, the MarketScan data cover only a subset of the population covered by the CPI. Second, MarketScan pharmaceutical data includes only mail-order or retail prescription drug claims and does not capture drugs dispensed in hospitals, outpatient clinics, and physician offices (although it may capture some “brown bagging”). Finally, we are unable to treat generic drugs as equivalent to brand drugs the way the BLS does in its computations. However, as discussed in Section V below, we believe these limitations have only modest effects on our estimates

To calculate the CPI with the MarketScan claims data, we compute a chained Laspeyres index using the following equation:

$$P_{t_n} = \frac{\sum(p_{c,t_1} \cdot q_{c,t_0})}{\sum(p_{c,t_0} \cdot q_{c,t_0})} \times \frac{\sum(p_{c,t_2} \cdot q_{c,t_1})}{\sum(p_{c,t_1} \cdot q_{c,t_1})} \times \dots \times \frac{\sum(p_{c,t_n} \cdot q_{c,t_{n-1}})}{\sum(p_{c,t_{n-1}} \cdot q_{c,t_{n-1}})}$$

where  $P_{t_n}$  is the price index for period  $t_n$  and  $t_0$  is a base reference period that anchors the value of the series,  $p_{c,t}$  is the mean price of drug  $c$  in period  $t$ , and  $q_{c,t}$  is the quantity of drug  $c$  sold in period  $t$ . New drugs are excluded from this formula in the first period that they appear in the data set, and only begin to contribute to the index in the second period they exist in the data, when for purposes of intertemporal comparison price and quantity information is available from both the current and the previous period. Note that when a new drug is launched, regardless of the relative size of its launch price, it has an impact on the growth rate of the aggregate all-drug CPI-Rx index only to the extent that its price growth following its launch differs from the weighted average price growth of all other incumbent drugs in the price index program. Exiting drugs are included in the index for only those months their quantities sold are positive.



The BLS does not distinguish between specialty and non-specialty drugs and so it is difficult for us to know what share of specialty drugs are in the BLS sample. Although the BLS' CPI-Rx likely excludes almost all transactions when drugs are dispensed in clinics, physician offices, and hospitals (other than "brown bagging"), it likely includes at least some transactions involving self-administered specialty drugs (e.g., the antipsychotic generic olanzapine, branded Zyprexa™, the antidepressant generic aripiprazole, branded Abilify™, or the frequently auto-injected anti-arthritis biologic, Humira™). The MarketScan claims data set encompasses a considerably larger set of prescription drugs than is in the BLS CPI-Rx sample.

Using the IQVIA classification framework, we can identify whether the MarketScan claim for a particular dispensed drug transaction involves a specialty or a non-specialty drug and whether that specialty or non-specialty drug was a generic or brand drug. We expect most specialty drugs in the MarketScan data set would not be included in the BLS' CPI-Rx sample, but we do not know the proportion that are. We use bootstrapping methods to determine the effects of under-sampling of specialty drugs—i.e., for each specialty sampling rate we examine (5%, 25%, 33%, and 50%), we simulate the random sample 10,000 times. This method also establishes confidence bounds around these estimates. Following the BLS' chained Laspeyres framework, we also produce separate aggregate price indices for brand-specialty, generic-specialty, brand-non-specialty, and generic-non-specialty drugs. This allows us to investigate the effect that changing the specialty sampling rate has on the sub-indices that make up the all-drug CPI-Rx.

We hypothesize that specialty drugs are under-sampled in the BLS CPI-Rx. One reason why low rates of sampling may affect estimates has to do with the specific circumstances of specialty drugs. That is, spending on specialty prescription drugs is highly skewed. So if one samples prescriptions at a low rate (5%), one can easily miss very expensive drugs with high rates of price growth. For example, as will be shown below, if one excludes Humira, one of the highest cost and highest price growth products, from the sample, the price index for specialty

brand drugs drops 7%. Estimating a CPI-Rx using MarketScan claims allows us to compare the BLS CPI-Rx to a more fully representative but still incomplete CPI-Rx that incorporates some purchases of specialty drugs. Changing the sampling rate of specialty drugs in the MarketScan CPI-Rx gives us the opportunity to investigate the relationships between growth rates of a more fully representative CPI-Rx vs. that of a CPI-Rx that under-samples specialty drug transactions.

#### IV. RESULTS

The non-seasonally adjusted published BLS CPI-Rx has a cumulative annual average growth rate (CAGR) of 2.99% for the January 2010 through December 2019 period.<sup>29</sup> Our fully representative CPI-Rx which includes all specialty and non-specialty retail and mail-order pharmaceutical claims from MarketScan has a CAGR of 3.64%. The more fully representative sample therefore has a CAGR 22% higher than the BLS CPI-Rx (0.65 percentage points higher). The total drug MarketScan CAGR is reduced when only a portion of specialty drugs are included in the sample. When we randomly sample specialty drugs at 50%, 33%, 25% and 5%, the total drug MarketScan CAGR decreases monotonically with decreasing sample specialty

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**Table 4. CAGR of total drug CPI when randomly sampling a set percentage of specialty drugs in MarketScan (2010-2019)**

<u>Sample</u>	<u>Simulations</u>	<u>CAGR</u>	<u>95% bootstrap confidence interval</u>
<b>100% MarketScan specialty drugs</b>	-	3.64%	-
<b>50% specialty drugs</b>	10,000	3.36%	(3.35%, 3.37%)
<b>33% specialty drugs</b>	10,000	3.23%	(3.23%, 3.24%)
<b>25% specialty drugs</b>	10,000	3.20%	(3.20%, 3.20%)
<b>5% specialty drugs</b>	10,000	3.08%	(3.08%, 3.09%)

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<sup>29</sup> U.S. Bureau of Labor Statistics [2022b], Series ID: CUUR0000SEMF01. Prescription drugs in U.S. city average, all urban consumers, not seasonally adjusted.

proportions to 3.36%, 3.23%, 3.20%, and 3.08%, respectively (Table 4.). So, for example, we estimate that if the BLS CPI only captures 25% of specialty drugs, it understated true CPI-Rx inflation by 0.44 percentage points over 2010-2019 (3.20% with a 25% sampling of specialty drugs in Table 4 below vs. official BLS CPI-Rx of 3.64%).

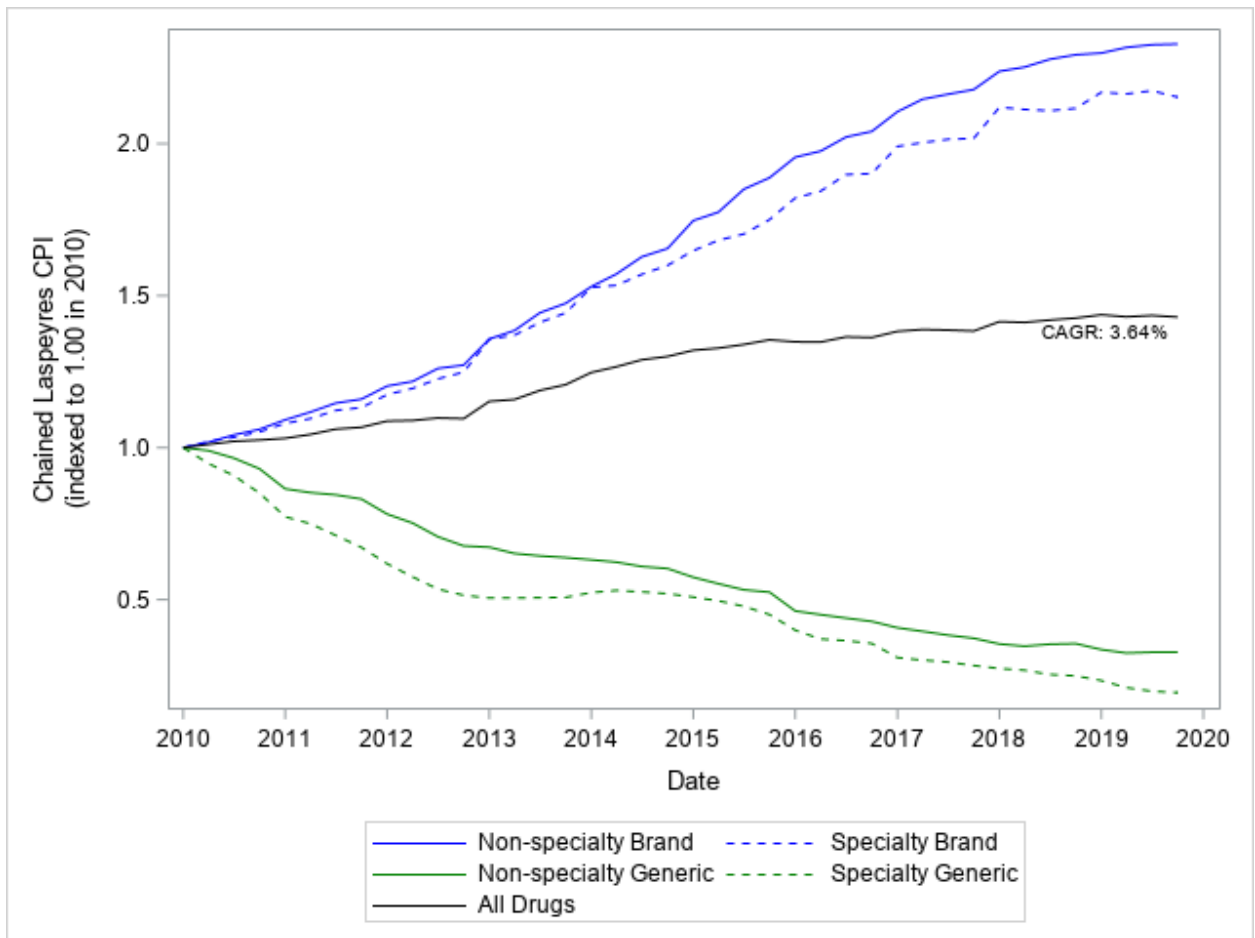
When we construct sub-indices of the drug CPI using MarketScan claims, we find that prices of brand drugs rise over time while generic drug prices fall (Figure 1). Specifically, we construct four separate price indexes by type of drug, assuming that all specialty drugs are sampled in the brand specialty and generic specialty calculations. Surprisingly, non-specialty brand and non-specialty generic prices rise faster than the corresponding specialty prices. This may be due to high launch prices of specialty drugs (which are not captured in a chained Laspeyres index) but is consistent with data produced by IQVIA [2022] showing that overall drug spending growth was driven by new products, especially biologics that are overwhelmingly specialty products. Because new products are a considerably larger share of specialty products compared to all branded drugs, that means the share of generic drugs in the specialty category will be much smaller than in the non-specialty drug grouping. Thus, when the aggregate price index is calculated the weight given to generic drugs is lowered by enlarging the specialty sample. This is what causes the aggregate index to rise as the specialty sample grows even though branded specialty prices are growing more slowly than are other brands.<sup>30</sup> Our central concern is that the possible under-representation of specialty drugs in the prescription drug CPI results in an under-estimate of the growth in specialty drug prices that in turn lowers the growth rate of the overall prescription drug CPI. The rapid growth in specialty products – frequently biological products -- is a relatively new phenomenon. That means that most specialty products will be newer and will also be less likely to face generic competition. Recall that the CPI-Rx is a

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<sup>30</sup> Ridley and Lee [2020] offer one possible explanation for higher launch prices. They show that incentives created by Medicare Part B reimbursement based on past average sales price (ASP) create an incentive for a high launch prices and lower subsequent price increases.

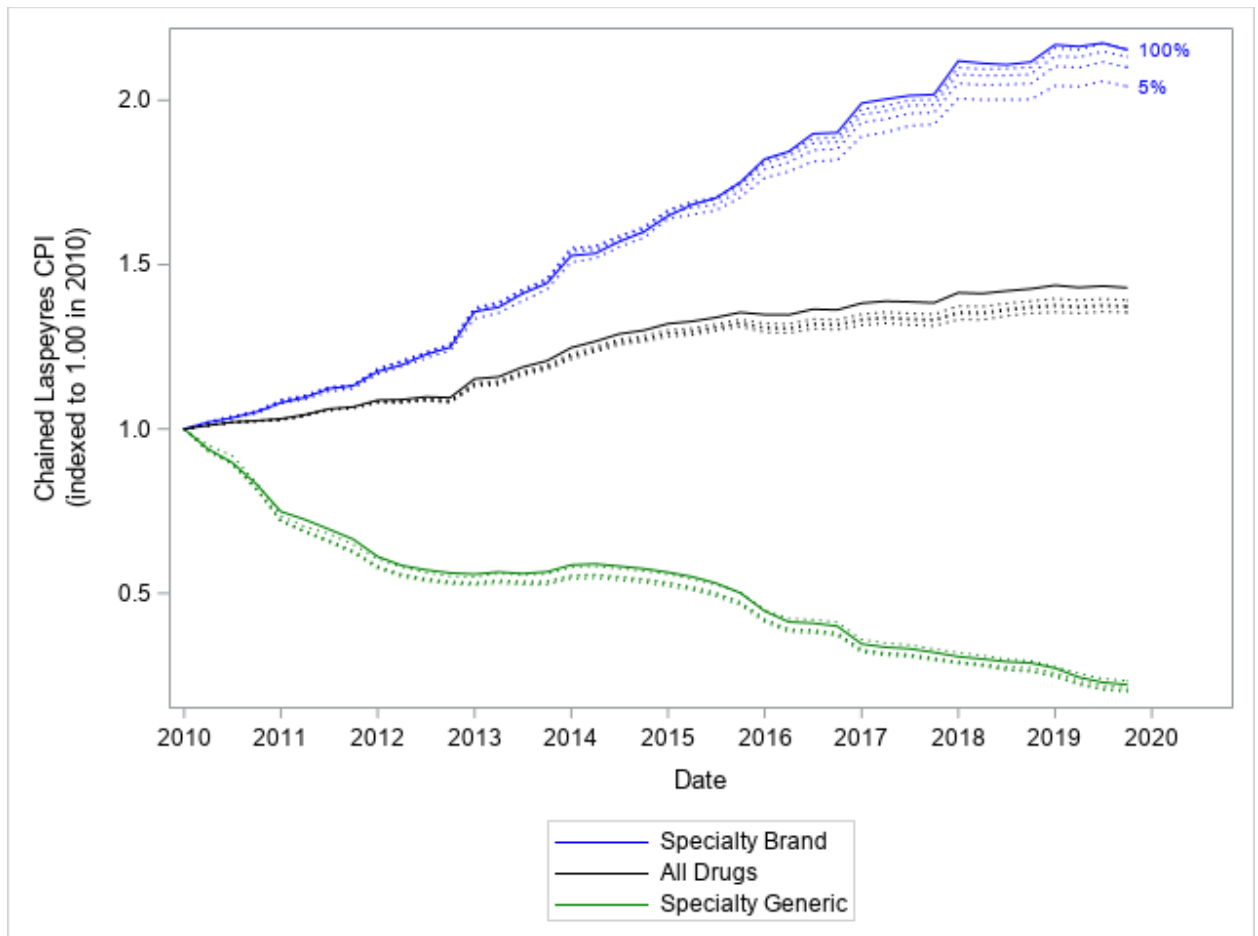
weighted average of branded and generic product price growth. Thus, as we increase the sample of specialty drugs it will increase the weight put on brand name drug price increases and give less weight to generic products, thereby potentially driving up the overall drug price index. Our data show that as the specialty drug sample is reduced, the ratio of branded to total spending declines. For example, in 2019, 92% of specialty spending was on branded drugs compared to 70% of non-specialty spending. Overall, 77% of spending was on branded drugs in 2019. If we randomly include only 25% of specialty drugs, the percentage of overall spending on branded drugs drops to 71%. The fewer specialty drugs included in the sample, the lower the overall percentage of spending is on branded drugs.

**Figure 1. Chained Laspeyres CPI for all prescription drugs in MarketScan, by drug type (2010-2019).**

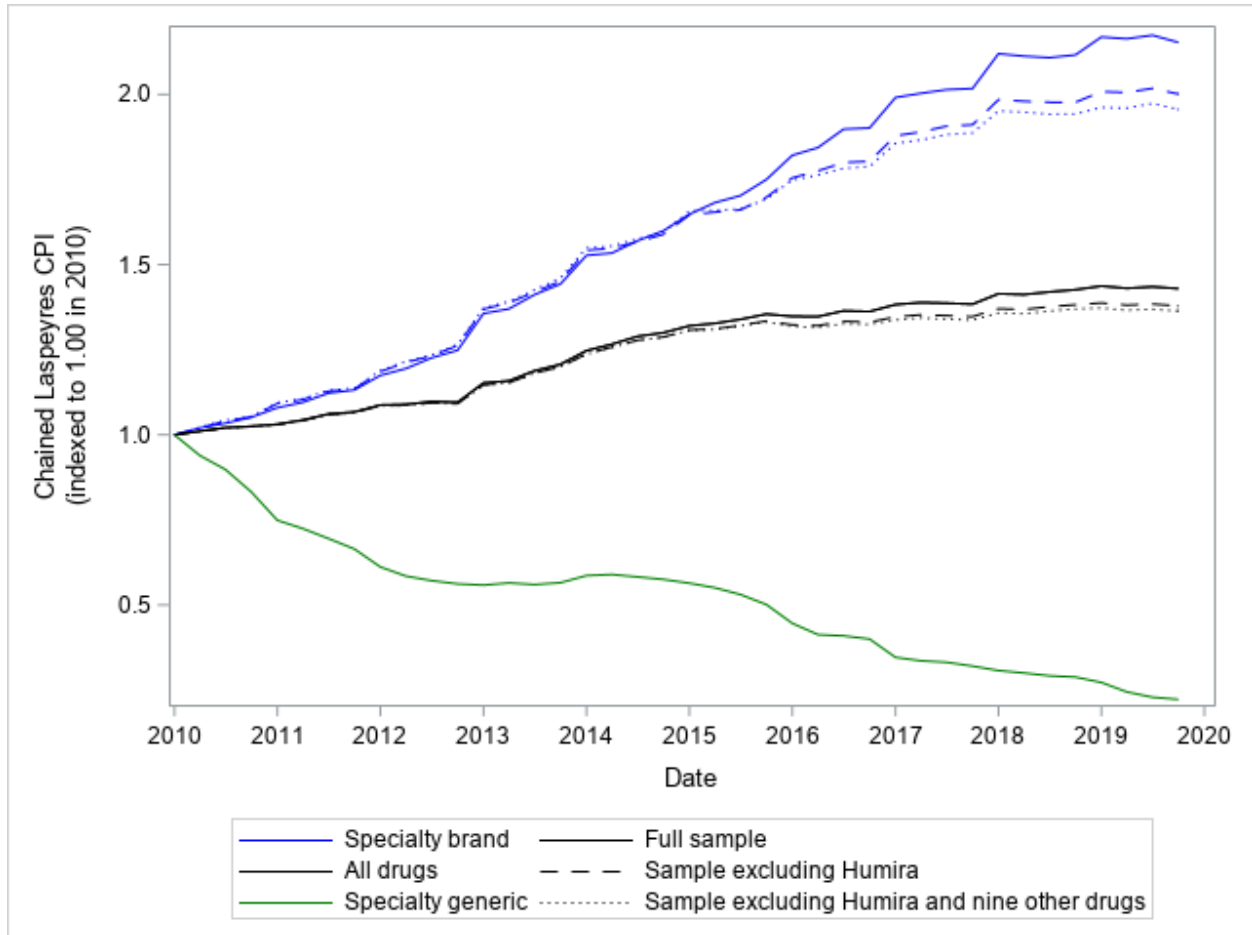


The evidence reported earlier suggests that sampling of specialty drugs is likely to be quite low. Figure 2 reflects our analysis of how disaggregated and overall drug CPIs are affected by reducing the sampling rate for specialty drugs. Allowing the sampling rate of specialty drugs to change for the disaggregated price indices, we find that as the sampling rate decreases the specialty-brand index falls. The blue hashed curves on Figure 2 show how the specialty-brand CPI curve shifts downward as the sampling rate decreases. As posited earlier, we interpret this as reflecting random sampling of prescriptions when the spending and price distributions are highly skewed. The specialty-generic index mostly stays the same, resulting in a downward shift in the overall prescription drug CPI. The black hashed curve on Figure 2 reflects the impact on the overall prescription drug CPI of lowering the specialty sampling rates. Figure 3 illustrates the issue by removing the ten highest cost specialty brand drugs from the index. The blue hashed curve shows the substantial reduction in the index curve when Humira is removed. The blue dotted curve shows further reduction in the CPI when Humira and the nine other highest cost specialty drugs are removed from the index. Though these ten drugs are less than 1% of the total number of specialty brand drugs, any sample of specialty drugs that does not include these high cost and high price growth products will underestimate the specialty drug price index. Hence, even when the random sample is simulated 10,000 times most iterations will not include these drugs. Table 5 shows the 95% bootstrap confidence intervals of the disaggregated CAGR when sampling 5%, 25%, 33%, and 50% of specialty drugs. The confidence intervals are widest when sampling the lowest percentage of specialty drugs, highlighting the sensitivity of the CAGR to sample selection. The confidence interval when randomly selecting 5% of specialty drugs is more than three times the size of the confidence interval when randomly selecting 50% of specialty drugs. Sampling from a smaller set introduces wider sampling error.

**Figure 2. Simulated changes in chained Laspeyres drug CPI from altering the sampling rate of specialty drugs in MarketScan from 100% to 5% (2010-2019).**



**Figure 3. Simulated changes in chained Laspeyres specialty brand drug CPI when removing the ten highest cost specialty branded drugs (2010-2019).**



**Table 5. CAGR of specialty-brand and specialty-generic sub-indices when randomly sampling a set percentage of specialty drugs in MarketScan (2010-2019)**

<u>Sample</u>	<u>Simulations</u>	<u>CAGR</u>	<u>95% bootstrap confidence interval</u>
<b>100% specialty brand drugs</b>	-	7.97%	-
<b>50% specialty brand drugs</b>	10,000	7.98%	(7.97%, 8.00%)
<b>33% specialty brand drugs</b>	10,000	7.89%	(7.87%, 7.91%)
<b>25% specialty brand drugs</b>	10,000	7.81%	(7.78%,7.83%)
<b>5% specialty brand drugs</b>	10,000	7.32%	(7.27%, 7.36%)
<u>Sample</u>	<u>Simulations</u>	<u>CAGR</u>	<u>95% bootstrap confidence interval</u>
<b>100% specialty generic drugs</b>	-	-15.13%	-
<b>50% specialty generic drugs</b>	10,000	-14.79%	(-14.81%, -14.77%)
<b>33% specialty generic drugs</b>	10,000	-14.69%	(-14.73%, -14.66%)
<b>25% specialty generic drugs</b>	10,000	-14.58%	(-14.62%, -14.54%)
<b>5% specialty generic drugs</b>	10,000	-13.40%	(-13.50%, -13.31%)

## V. SUMMARY, LIMITATIONS, AND IMPLICATIONS

### V.A. SUMMARY

We have documented that BLS procedures for its Consumer Price Index Prescription Pharmaceuticals (CPI-Rx) program explicitly state that CPI-Rx limits its sampling procedures to retail outpatient outlets, such as chain drug stores, independent pharmacies, mail pharmacies, mass merchandisers with pharmacies, supermarkets with pharmacies, and possibly specialty



pharmacies. This retail-focused sampling frame excludes sales of prescription pharmaceuticals dispensed in hospitals, physician/clinic outpatient facilities, and institutional non-retail health care sites such as long-term care facilities and nursing homes. While this retail sampling focus likely captures the vast majority of sales of traditional, small-molecule self-administered oral solid pharmaceuticals, as well as many self-administered non-oral pharmaceutical formulations such as inhalants, ointments, suppositories and some self-administered injectables or infusible products, it overlooks the increasingly important specialty pharmaceuticals dispensed in hospitals, outpatient clinics, and physician offices, consisting of biologics and orphan drugs often administered by health care professionals. Instead, hospital sales of specialty drugs that amount to roughly 40 percent of specialty products are typically captured in the overall hospital component of the medical CPI and not in the CPI-Rx component. Similarly, sales to physician offices and clinics that account for almost 40 percent of specialty products are typically included in the physician and professional services component of the CPI, and not in the CPI-Rx component. While our data does not include pharmaceuticals dispensed outside retail pharmacies, we note that excluding only the ten most dispensed specialty drugs in MarketScan over our ten-year study frame decreases the overall CPI-Rx from 1.43 to 1.36, a proportional decrease of about 5 percent.

The principal focus of our empirical effort involves quantifying the consequences for the estimated growth of overall prescription pharmaceutical price inflation had the BLS' CPI-Rx program expanded its sampling domain from retail-only to retail plus non-retail dispensing establishments such as hospitals, outpatient clinics, and physician offices -- establishments that increasingly dispense specialty pharmaceuticals. We do not know, nor does the BLS know, what proportion of prescription pharmaceuticals in its sampling frame are specialty pharmaceuticals, nor do we know how price growth of specialty pharmaceuticals has differed from that of traditional pharmaceuticals. We therefore use the IBM MarketScan™ Commercial

Claims and Encounters Research Database for the years 2010-2019 containing mail-order or retail program pharmaceutical claims for approximately 25-40 million people annually under age 65. We identify claims involving specialty drugs in this database using a list of drugs identified by the IQVIA Institute for Human Data Science as specialty drugs and classify all the remaining pharmaceutical claims as involving non-specialty, traditional drugs. We do not know whether a particular drug in the IBM-MarketScan™ data base is in scope for the BLS's CPI-Rx, but we expect only a small proportion of specialty drugs identified in the IBM-MarketScan™ data base is in scope for the BLS's CPI-Rx. We therefore alternatively vary the sample rate of specialty drug transactions in the IBM-MarketScan™ database at 5%, 25%, 33%, 50% and 100%; we expect the 5% sample rate most closely approximates current BLS protocols, since we have learned that several well-known central nervous system drugs are classified by IQVIA as specialty drugs, suggesting that the BLS-Rx sample frame likely includes at least some specialty drugs. We create alternative simulated data bases – consisting of traditional or non-specialty brand, non-specialty generic, specialty brand and specialty generic -- and calculate the compounded average growth rate (CAGR) of the aggregate price index for that database between 2010 and 2019. For each of these alternative specialty samples, we utilize BLS' chained Laspeyres index number formulae<sup>31</sup>, and simulate each of the samples 10,000 times to generate confidence intervals.

Over the 2010-2019, the published BLS CPI-Rx grew at a compounded average growth rate (CAGR) of 2.99 percent. With the alternative IBM-MarketScan™ specialty drug transactions at 5%, 25%, 33%, 50% and 100% of the claims, the mean 2010-2019 CAGRs we obtain are 3.08 percent, 3.20 percent, 3.23 percent, 3.36 percent, and 3.64 percent respectively. Notably,

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<sup>31</sup> A desirable property of the chained Laspeyres price index procedure is that it is consistent in aggregation – if one has  $n$  distinct data bases and from them creates  $n$  sub-aggregate price indexes using chained Laspeyres procedures, and then separately computes a Laspeyres chained aggregate of the  $n$  sub-aggregate price indexes, one obtains the same aggregate price index measure. For discussion, see Diewert [1978].

our 5% sample of IBM-MarketScan™ transactions (that we believe most closely mimics current BLS CPI-Rx procedures) generates a CAGR of 3.08 percent, very close to the BLS' official CPI-Rx CAGR of 2.99 percent. Had the BLS sample included 100 percent of the IBM-MarketScan™ specialty drug claims as well as all IBM-MarketScan™ non-specialty drug claims, the all-drug claims CAGR would have been 3.64 percent, a 0.65 percentage point increase above the official 2.99 percent calculation (a 22 percent more rapid growth rate than the official BLS CPI-Rx).

These results suggest therefore, that by focusing only on a sampling frame that under-samples specialty pharmaceuticals, the BLS CPI-Rx program is understating the price growth of an all-pharmaceutical channels price index, with the understatement being almost 75 basis points annually.

#### V.B. LIMITATIONS

Several limitations to our research exist that could affect the reliability of our almost 75 basis point understatement finding. Four deserve explicit attention, three involving the the IBM-MarketScan™ Commercial Claims and Encounters Research DataBase, and the other an index number calculation difference from that used by the BLS.

The first limitation involves which drugs appear in our sample. MarketScan pharmaceutical data includes only mail-order or retail prescription drug claims. Many specialty pharmaceuticals are dispensed in hospitals, outpatient clinics, and physician offices. There is, however, evidence that we are capturing at least some specialty drugs administered in a facility through the practice of "brown-bagging". Specifically, in 2019, MarketScan contained \$3 million in spending on the oncology drugs Keytruda, Opdivo, Avastin, and Perjeta. These drugs need to be administered through an IV infusion. We believe that these and other specialty drugs are

being dispensed from a pharmacy directly to the patient, who then transports the medication to a physician's office or infusion clinic for administration.

We believe that this limitation causes us to underestimate the potential downward bias in the pharmaceutical CPI. In fact, based on price indexes constructed for physician and clinic administered drugs by MedPAC the evidence suggests that our estimates likely represent a lower bound estimate of the consequences of under counting specialty drugs. The MedPAC July 2022 Data Book reports a price index for Medicare Part B drugs. The index for biologicals indicates that over the period 2010 through 2020 Part B biologics prices increased by a factor of 1.37. In contrast the overall drug CPI grew by 1.30 suggesting a downward effect of under-sampling special drugs- like brand name biologicals.<sup>32</sup>

Regarding representativeness, our claims data derive from what insurers call commercial claims, as distinct from non-commercial claims databases such as those from beneficiaries covered by Medicare, Medicaid, and Veterans' Administration (VA) programs. *A priori*, we do not know if restricting our claims to commercial biases upward or downward our estimated almost 75 basis point understatement finding. While the various federal government prescription drug benefit programs (Medicare, Medicaid, and VA) are known to have secured price concessions for prices at the time of launch of new drugs, the literature on relative growth of price changes (as opposed to price levels) is less voluminous and has ambiguities.<sup>33</sup> Nevertheless, recent reports from MedPAC [2022] show that specialty drug spending under Part B of Medicare is growing rapidly. They conclude that increased prescription drug spending in Part B of Medicare is due to both specialty drug price increases and launch of new expensive products.<sup>34</sup> Further exploration of these phenomena is warranted. It is worth noting, however,

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<sup>32</sup> [https://www.medpac.gov/wp-content/uploads/2022/07/July2022\\_MedPAC\\_DataBook\\_SEC\\_v2.pdf](https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_SEC_v2.pdf)

<sup>33</sup> For an important exception involving Medicaid procurement and rebate policy, see Duggan and Scott-Morton [2006].

<sup>34</sup> MedPAC [2022].

that the prices reported in the claims data we employ are those received by the dispensing pharmacies (the sum of reimbursements from third party payors to pharmacies, plus the cash, out-of-pocket payments from pharmacy customers), and are not prices that directly reflect rebates from manufacturers to Medicaid, Medicare Part D Prescription Drug Plans, and commercial plans. Notably, recent reports from the Congressional Budget Office show that rebates for specialty drugs in Medicare Part D are considerably smaller than those for branded prescription drugs overall.<sup>35</sup>

A second representativeness issue involves our claims data excluding beneficiaries over age 65, both from commercial and non-commercial plans. Based on rather old data from the early to mid-1990s, there is a literature suggesting minimal and non-material differences in prescription drug price inflation for drugs destined for consumption by the elderly vs. the non-elderly [Berndt, Cockburn, Cocks et al. (1998a,b)], but changes in elderly prescription drug benefits have been monumental since the late 1990s (e.g. passage of the Medicare Modernization Act and its implementation in 2006). There is also a literature documenting that the Medicare Drug Part D benefit affected overall drug utilization and drug prices, particularly in drug classes experiencing aggressive therapeutic competition [Duggan and Scott-Morton (2010, 2011)]. We have no evidence on which to conclude that restricting our beneficiary sample in the IBM-MarketScan™ database biases upward or downward our estimated almost 75 basis point understatements finding. Each of these representativeness topics is worthy of further investigation using updated and more stratified data.

Our third limitation involves the treatment of generic drugs. Since 1995, the BLS has implemented procedures that link the price of a prescription pharmaceutical just losing patent or other market exclusivity protection to the launch prices of entering generic drugs, implicitly

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<sup>35</sup> Anderson-Cook, Maeda, and Nelson [2019].

considering the brand and generic as perfect substitutes, and treating the switch from higher priced brand to lower priced generic as a price reduction.<sup>36</sup> Our use of the chained Laspeyres index does not link the generic to the brand price at time of patent expiration, but instead treats the generic as a new good and only considers post-launch price changes for the generic. This likely results in an upward bias to the almost 75 basis point understatement finding, i.e., if we introduced BLS-like procedures, we would likely find a smaller than 75 basis point understatement. We believe this upward bias is likely quite small, for several reasons. First, when we use the 5 percent specialty sample that most closely mimics BLS specialty drug sampling, our CAGR estimate of 3.08 percent is very close to the official BLS CPI-Rx CAGR of 2.99 percent. Second, because of the evolution of industry responses to provisions of the 1984 Hatch-Waxman legislation, the last decade has seen most drugs losing market exclusivity only facing limited competition and price declines initially, followed by a period of much more intense competition and experiencing much greater price declines.<sup>37</sup> As a result, our procedure that excludes the first month of generic entry but includes months two and all following months likely captures most of the generic price decline and link from brand to generic. Nonetheless, we acknowledge our treatment of generic entry likely exaggerates the almost 75 basis point understatement finding. Although we are unable to mimic BLS procedures using the claims data in the IBM-MarketScan™ data base, we believe quantification of the bias in our procedure may be possible using procedures utilized by, for example, Ellison, Cockburn, Griliches and Hausman [1997].

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<sup>36</sup> For discussion, see U.S. Bureau of Labor Statistics [2018], p. 23; U.S. Bureau of Labor Statistics [2022a], p. 5/7; U.S. Bureau of Labor Statistics [2011b], pp. 12-13; and Berndt, Cockburn and Griliches [1996].

<sup>37</sup> See Aitken, Berndt, Bosworth, Cockburn, Frank, Kleinrock and Shapiro [2018] for empirical analyses.

## V.C. IMPLICATIONS

The BLS' CPI-Rx price indexes are widely used for a variety of purposes, ranging from contract provisions penalizing a manufacturer if its portfolio of drugs has price increases more rapidly than the BLS' CPI-Rx, to public policy debates and controversies involving whether the market power of retail outlets, wholesalers, pharmaceutical benefit managers, or other intermediaries are raising pharmaceutical prices more rapidly than the All-Items CPI-U, to debates and public policy controversies on whether manufacturers' list or net of rebate price increases are greater or smaller than those charged in retail outlets.

The extent to which the BLS's current CPI-Rx metric is accurately measuring prescription price changes obviously depends on the question being asked, the distribution channels involved, and the perspective of the seller, buyer, or intermediary within the distribution channel. To the extent issues being considered are limited to prices received by retail outlets and largely self-administered traditional drugs, the current CPI-Rx program may be adequately informative and reliable. However, to the extent issues being considered concern the pharmaceutical industry in its entirety – for drugs dispensed in both retail and non-retail settings, the current CPI-Rx may not be as informative or reliable.

The analyses presented here document that the approach to data collection used by the BLS' CPI-Rx yields estimates of the prescription drug sub-index that are incomplete for the purpose of understanding overall price growth in prescription drugs and ultimately for tracking spending. It also highlights the fact that the prices of some drugs can be growing quite rapidly while others are falling. So, debates about drug prices and spending growth cannot be settled by relying on data that excludes important segments of the market. In this research, we document that exclusion of many drugs dispensed in organized medical settings like clinics, specialty pharmacies, and physician offices and clinics will result in not obtaining data on many biological products and specialty pharmaceuticals. This is significant because spending on

these drugs is growing rapidly and now claim 55% of expenditures on prescription drugs (IQVIA [2022]).

A variety of policy efforts aimed at reducing the growth in spending on prescription drugs propose to link prescription drug spending to growth in the overall CPI. Assessing the likely consequences of such policies relies in part on making forecasts of price growth for prescription drugs. If those projections are based on historical price and spending data that do not completely account for all products on the market, the projections will likely be distorted. Our results show that by underweighting specialty drugs in the prescription drug CPI, the savings stemming from reducing price growth in prescription drugs may be substantially understated.

This raises the issue of whether the CPI-Rx program should be overhauled, and/or if greater efforts need to be made to inform users that the CPI-Rx should not be used as a representation of all drug prices. If the BLS attempts to “fix” the underrepresentation of specialty drugs in the CPI-Rx, then for consistency it likely must also address its possible current overrepresentation in the hospital and physician-professional components of the medical CPI. We suspect that the under-sampling of specialty drugs in the CPI-Rx program is not isolated to that sub-component. Our review of the CPI design suggests that much of the under-sampling of specialty drugs in the CPI-Rx component is captured in the hospital and physician-professional services sub-components. How complete the measurement of specialty drugs is in those other segments, however, is not clear. Thus, it is uncertain the extent to which the problem is simply one of the proper allocations of the appropriate number of specialty drug sample transactions into their specific sub-components. So, we inquire, given all the dramatic advances in the discovery and development of specialty medicines, changes in the distribution of specialty pharmaceuticals, and changes in the ownership of physician offices and clinics by hospitals, are numerous specialty pharmaceutical market developments not being promptly incorporated into the BLS’ medical CPI program? There is evidence at least consistent with the notion that the



BLS is capturing some of the specialty drug market penetration in its medical CPI. As noted earlier, between 2010 and 2021, the relative weight of medical care services (including hospitals and physician-professional services) in the medical care CPI increased from 75% to 82%, while the relative weight of the hospital and related services subcomponent within the medical care services component increased from 26% to 30%. In this context, it is worth noting a recent study authored by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) analyzing the Medicare Part B program suggests it is possible that the rapidly growing spending on physician-administered drugs is contributing to physician expenditure growth. Between 2006-2017, expenditures per beneficiary increased by about \$1700, with about \$400 of that increase being due to greater spending on drugs.<sup>38</sup> The ASPE study highlights that if one wants to “fix” the under-sampling in the CPI-Rx, it may be necessary to examine whether CPI-hospitals and CPI-physicians and professional services also need to be “fixed”. Moreover, as noted earlier, the allocation of transactions prices into multiple inputs (analogous to specialty pharmaceutical transactions being allocated to pharmaceuticals, hospitals, and physician-professional services) is not unique to pharmaceuticals but is also an issue in other medical CPI components, such as the allocation of a hospital visit involving insertion of a pacemaker into hospital, equipment, and physician services components.

The discussion in the previous paragraph makes it clear that “overhauling” the CPI-Rx and making it still be consistent with other parts of the medical CPI may be a much more complex and complicated exercise than originally envisaged. This makes a second policy alternative more attractive, and that is that the BLS CPI program publish an additional index for all prescription drugs, separate from its current retail prescription drug price index. It is worth noting the BLS currently publishes several special index aggregates, such as an all items less food and energy, commodities less food and energy commodities, and services less energy

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<sup>38</sup> Nguyen and Sheingold [2020].

services index. One possibility worth examining is whether it is feasible, given its current sampling frames for the BLS to collect and publish an overall pharmaceutical price index incorporating both traditional and specialty pharmaceuticals dispensed in retail and non-retail establishments.

## VI. CONCLUDING REMARKS: AN HISTORICAL PERSPECTIVE

In part because of their relevance to informing public and private sector policies, U.S. federal government statistics – particularly the Consumer Price Index -- have long been closely scrutinized, going back at least to Congressional hearings held by the Joint Economic Committee in 1961.<sup>39</sup> A more recent example is the 1998 Boskin Commission on Price Statistics<sup>40</sup>, followed shortly thereafter by an evaluation by the National Research Council Committee on National Statistics.<sup>41</sup> A useful overview and historical perspective is the “Review of Reviews: Ninety Years of Professional Thinking About the Consumer Price Index” by Reinsdorf and Triplett.<sup>42</sup>

A common conclusion in the evaluations of the CPI is that historically it has often displayed an upward bias and overstated inflation, although that has not always been the case such as during times of military conflict and shortages; see, for example, Reinsdorf and Triplett [2009], Schultze and Mackie [2002], and Moulton [1996]. In contrast, the research reported here suggests that in one sector – the prescription pharmaceutical market – the relevant CPI may recently have understated price growth. The possible bias we examine involves under-sampling of rapidly growing non-retail medical outlets that dispense high and rapidly price increasing specialty drugs. A different bias – in the BLS’ Producer (not Consumer) Price Index program –

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<sup>39</sup> U.S. Congress, Joint Economic Committee [1961].

<sup>40</sup> Boskin, Dulberger, Gordon, Griliches, and Jorgenson [1998].

<sup>41</sup> Schultze and Mackie [2002].

<sup>42</sup> Reinsdorf and Triplett [2009]. For an historical overview of medical price measurement issues, see Berndt, Cutler, Frank, Griliches, Newhouse and Triplett [2000].

involved apparent oversampling of old prescription drugs whose prices were rising more rapidly than those of newer drugs; this was the focus of an early 1990s study by Berndt, Griliches and Rosett [1993].

If there is a consistent theme among these various studies, it is that because of rapid scientific and technological developments, along with institutional changes in how goods and services are distributed and where they are purchased and consumed, government price statistic programs need to adapt their data gathering methods frequently to ensure the sampled goods and services accurately portray a continuously evolving marketplace. Overestimation and underestimation of aggregate price changes are each possible – the sign of the bias is generally indeterminate. Moreover, while particularly important in the medical and health care sector, this measurement challenge is likely pervasive in many technology-intensive market contexts.

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