MEDICARE PART D, PRESCRIPTION DRUG PRICES,

AND TREATMENT QUALITY

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I. Introduction

Congress passed initial versions of the Medicare Prescription Drug, Improvement and Modernization Act in late June 2003. This landmark legislation provided for a prescription drug benefit for all over age 65 Medicare beneficiaries, and also for individuals under age 65 having certain disabilities. This new prescription drug benefit was called Medicare Part D. The House and Senate versions of the bill differed, and after considerable negotiations and maneuvering, the House passed a unified version of the bill by a 220-215 vote on November 22, 2003. On the next day the Senate passed the legislation by a 54-44 vote. President Bush signed the final conference committee version into law on December 8, 2003. The Medicare Part D prescription drug benefit was fully implemented beginning January 1, 2006.

The Congressional and public debate on the merits of this legislation was extensive and heated. Controversy surrounded issues such as, what would the effects be from moral hazard on prescription drug demand and prices? How should the federal government exercise its considerable buying power? How restrictive or broad should formularies be? How much competition should there be among private plans offering benefits? How high would monthly premiums be, and how would they vary with benefit design? And of course, how much would this new entitlement cost?

Medicare Part D has been with us now for a year. What has happened? In terms of assessing its impact on prescription drug prices, there are at least three important considerations, on which we focus in the first part of this paper. First, how has the U.S. Bureau of Labor Statistics, the source of official government price statistics, monitored prices paid by consumers (the Consumer Price Index), as well as prices received by manufacturers from sales to the first point in the distribution chain (Producer Price Indexes), subsequent to implementation of

Medicare Part D? Specifically, what measurement changes and assumptions were required in order to assess the impact of Part D on consumers' and producers' prices? Second, given provisions of the Part D legislation and the BLS' procedures for measuring prices, what do we expect regarding the impact of Part D on consumers' and producers' prices? And third, what price changes have been observed by the BLS' CPI and PPI indexes leading up to and then following full implementation of the Part D legislation on January 1, 2006?

While adjusting prices for quality change is important for many goods and services, it is widely thought that this is particularly important in the context of medical care; this point was emphasized most recently by the Boskin Commission, whose final report was issued a decade ago in December 1996.[1] Elsewhere several of us have argued that for medical care, what is ideally priced is the total treatment cost for an episode of care, taking outcomes into account; when the condition being treated is chronic rather than acute or episodic, a reasonable price measure is total treatment cost over a given time period, such as a year. Treatment of a chronic condition, however, magnifies the role of the duration and continuity of treatment. If medicines are an important component of long-term treatment, then issues of dosing also become prominent. Hence in the final part of this paper we report on recent preliminary research findings regarding the annualized cost of antipsychotic medicines used for the ongoing treatment of schizophrenia, where we focus in particular on quality attributes involving treatment dose and duration.

II. Background History and Literature

Over the years, as US public policy has lead to expanding health insurance coverage, policy analysts have focused not only on government and elderly out-of-pocket expenditures on health care, but also on the price and quantity components of these expenditures. Related

concerns have focused attention on the overall price inflation experienced by the elderly vs. the non-elderly, and more specifically on relative prices paid by the elderly vs. the non-elderly for health care goods and services.

For at least seven decades, the BLS' Medical CPI ("MCPI") has risen about half again as fast as the overall CPI; between 1927 and 1996, for example, the MCPI rose at an average annual growth rate ("AAGR") of 4.59%, compared with 3.24% for the CPI.[2] Between January 1996 and October 2006, these AAGRs were 3.86% and 2.50%, respectively. Congressional concern over these differential rates of inflation has involved a number of initiatives.

Prior to the introduction of Medicare in July 1966, the Social Security Administration anticipated that the existence of the new insurance might have an impact on medical care prices. Therefore, in summer 1965, the Administration arranged with the BLS to collect supplementary prices for three surgical procedures and two in-hospital medical services that were particularly prevalent among the elderly, though not necessarily limited to them. The three surgical procedures were cholecystectomy (removal of gall bladder), prostatectomy (removal of prostrate gland), and fractured neck of femure (hip surgery), while the two in-hospital services were acute myocardial infarction (treatment of heart attack) and cerebral hemorrhage (stroke). Among the results of this study, as stated in a report to the President and summarized by Dorothy P. Rice and Loucele A. Horowitz, was the finding that:

> The index of the five in-hospital surgical and medical procedures particularly significant for the aged did not increase as rapidly during 1966 as the combined index for physicians' fees regularly priced for the CPI.[3]

Several decades later, in response to a mandate contained in the 1987 amendments to the Older Americans Act of 1965, the BLS created an experimental price index for elderly consumers ("ECPI"). The ECPI employs differential expenditure weights for the elderly

(defined as households headed by persons aged 62 and older) and the non-elderly, based on data from the Consumer Expenditure Survey, but assumes that within each category weight, the distribution of prices, the outlets in which consumers buy, the use of coupons, and the availability of discounts, as well as the quality of the items purchased, are the same for the elderly and non-elderly. From 1982 through 1996, the ECPI for the elderly grew 67.9%, while the CPI rose 62.5%, implying that over that 15 year time period, the AAGR of the ECPI at 3.77% was slightly higher than the 3.53% for the overall CPI.[4] In the ten plus years since then, between January 1996 and October 2006, the AAGRs of the ECPI and overall CPI have been 2.68% vs. 2.50%, respectively. The larger health care expenditure weights for the elderly, along with greater measured medical price inflation, account almost entirely for the difference in AAGRs between these two series. In this context, one qualifying note emphasized by the Boskin Commission was that medical care prices are likely to have overstated inflation by not fully accounting for improvements in quality.[5] If this is correct, then as Brent R. Moulton and Kenneth J. Stewart have noted, "A reduced rate of inflation for medical care would mitigate and perhaps eliminate any difference between the CPI-E and the official CPI."[6]

Relatively little research has focused on price differentials between the elderly and non-elderly for health care goods or services.[7] Among various medical care goods and services, pharmaceuticals have become an increasingly important component of the medical care armamentarium. Moreover, prescription drugs are likely to be one case in which within-stratum consumption patterns of the elderly likely differ substantially from those of the non-elderly.

Berndt, Cockburn, Cocks, Epstein and Griliches [1998a,b] have examined whether prescription drug price inflation in the 1990s differed between the elderly and the non-elderly,

when age-related substrata variations in consumption were taken into account. They examined prices at three alternative points in the distribution chain, and reported three findings.

First, at the initial point in the distribution chain involving manufacturers' sales to wholesalers, retailers, and hospitals – transactions that are monitored and reported by various BLS producer price indexes ("PPIs") -- there is essentially no age-related aggregate price differential, despite very significant differences in the baskets of drugs ultimately destined for use by the elderly vs. the non-elderly. Specifically, using prescription drug data from the IMS National Disease and Therapeutic Index survey to record elderly vs. non-elderly number of prescriptions by therapeutic class, and applying these proportions to the BLS' PPI weights by therapeutic class, the authors found that the PPI index for pharmaceuticals destined for ultimate use by the elderly increased from 1.000 in 1990 to 1.331 in 1996, while that for the non-elderly rose from 1.000 to 1.329 over the same six-year time period.

A second finding focused on an intermediate point in the distribution chain, involving acquisition prices of retail pharmacies for purchases primarily from wholesalers as measured by the IMS Retail Prescription Audit; these retail sell-in transactions take place at a point in the distribution chain that is in between the PPI and CPI, and is not monitored by BLS price measurement programs. The authors focused on three therapeutic areas – antidepressants (used twice as intensively by the non-elderly vs. elderly, 4.69% vs. 2.35%), broad and medium-spectrum antibiotics (also used about twice as intensively by the non-elderly vs. elderly, 15.79% vs. 7.44%), and calcium channel blockers (for hypertension, used about three times more intensively by the elderly vs. non-elderly, 6.18% vs. 2.01%). The authors found that between 1990 and1996, retail acquisition price inflation for antidepressants destined for use by the elderly at 7.02% was less than that for ultimate use by the non-elderly at 10.9%. Further research

revealed that the elderly disproportionately used older generic drugs, whose prices rose less rapidly than brands during this time period.

For antibiotics, however, especially from 1992 onward, the reverse occurred – the elderly antibiotics price index increased 7.74%, whereas that for the non-elderly only rose 2.40%. Additional research suggested that the greater elderly price inflation since 1992 appeared to reflect the more rapid growth in the elderly's use of the newest, branded drugs, for which bacterial resistance was generally less likely. Finally, for the calcium channel blockers, there was essentially no difference in price inflation between 1990 and 1996 – 10.0% for the non-elderly vs. 11.1% for the elderly.

Data constraints prevented Berndt et al. [1998a,b] from undertaking a comparable analysis of retail sell-out prices across various therapeutic classes. Instead, the authors confined their analysis of sales by retail pharmacies to consumers and other payors (monitored by IMS' method-of-payment survey) to the antidepressant therapeutic class. Over all age groups, between 1991 and 1996 gross margins for antidepressants sold by retail pharmacies (sell-out relative to sell-in prices) fell about 3.5%, due in part to the growth of managed care and pharmaceutical benefit manager firms during that time frame. Additional research found that young consumers appeared to have enjoyed most of the benefits of the increased buying power of managed care, for gross margins on the antidepressants they purchased fell by 3.8%. In contrast, for the antidepressants purchased by the elderly who are disproportionately large users of generic drugs, retail margins actually increased slightly.

These results suggest that no general age-related pattern of price inflation differentials for prescription pharmaceuticals is likely to emerge. Instead, the empirical significance of brand vs. generic consumption, of the use of new vs. old drugs, and of various age-related quality

attributes (once-a-day vs. multiple daily dosages, extent of adverse interactions with other drugs, and seriousness of side effects and adverse reactions) must most likely be examined on a class-by-class basis before any general conclusions can be reached. Moreover, even these class-specific variations may change with time, particularly when major institutional and market changes take place.

An example of such a major legislative development is the Medicare Prescription Drug, Improvement, and Modernization Act, which was passed by the US Congress in 2003, mandating a Medicare Part D prescription drug benefit for the elderly and disabled, beginning January 1, 2006.

III. Medicare Part D: Timelines, Essential Features and BLS Price Measurement

A. Legislative History and Essential Features

The Medicare Prescription Drug, Improvement and Modernization Act ("MMA") was introduced into the House of Representatives on June 25, 2003, sponsored by Speaker Dennis Hastert. After an initial electronic vote failed, several Republicans changed their vote, and early on the morning of June 27, 2003, it passed by a 216-215 vote. The Senate passed its version of the bill by a 76-21 vote on June 26, 2003. The bills were then unified in a conference committee, and came back to the House for approval on November 21, 2003. After various legislative maneuvers and vote changes by congressional representatives, around 5:30 am on November 22, 2003, the House passed the unified bill by a 220-215 vote. The Senate's consideration of the conference report was less heated but still controversial, and the bill finally passed the Senate by a 54-44 vote on November 23, 2003. President Bush signed the bill into law on December 8, 2003.[8]

Under the MMA of 2003, a new prescription drug benefit, called Medicare Part D, was to become available beginning January 1, 2006, whereby Medicare beneficiaries and the disabled under age 65 would receive a statutorily defined standard prescription drug benefits after a $250 annual deductible, would pay 25% of costs up to $2,250, 100% of costs between $2,250 and $5,100 (a gap of $2,850, commonly referred to as the "Donut Hole"), and 5% of costs above $5,100. Plans were granted freedom to construct alternative benefit designs that were actuarially equivalent to the standard benefit, such as no deductibles and tiered copayments rather than 25% coinsurance.[9] Monthly premiums were estimated to be about $37, with variations depending on copayment structures, formulary design, and retail pharmacy network benefit provisions.

As a temporary and transitional step to assist beneficiaries more immediately with their prescription drug purchases, the MMA of 2003 also created a program whereby Medicare approved discount cards were issued to beneficiaries for use beginning on June 1, 2004. These cards were to help seniors purchase lower-priced prescription drugs until the full Part D benefit was implemented in January 2006. The discount cards were not actual insurance but instead were cards issued by Medicare-approved private sector entities (pharmacies, pharmacy benefit management firms, insurers) giving Medicare beneficiaries approximately a 15-20% discount on out-of-pocket cash prices for prescription drugs; discounts were on the steeper end for generic drug purchases.[10] Other important dates were October 1, 2005, the first day for private companies to release details of their individual plans, and November 15, 2005, the first day that individuals could enroll in a Part D prescription drug plan.

One other significant aspect of the MMA of 2003 concerned those individuals over age 65 who had been receiving prescription drug benefits under various state Medicaid programs, and those under age 65 with certain disabilities. These "dual eligible" beneficiaries were all

transferred from Medicaid to the Medicare Part D program, effective January 1, 2006. It is estimated that these dual eligibles accounted for about 29% of all Part D enrollees.[11] Under the Medicaid "most favored nation" rules, manufacturers had been (and still are) required to offer Medicaid the lowest price they sell to the private sector minus 15.1% for brands.[12] Under Medicare Part D, however, pharmaceutical manufacturers instead negotiated prices with private prescription drug plans ("PDPs"), whose ability to extract price concessions is likely considerably less than that of Medicaid.[13]

B. Medicare Part D Price Monitoring by the BLS

Given the substantial lead time between initial legislative approval in June 2003 and final full implementation of Medicare Part D in January 2006, the various BLS price measurement programs had considerable time to adapt their data collection and aggregation procedures as necessary to reflect changing prices associated with implementation of Medicare Part D.

Since the PPI measures prices only at the first point in the distribution chain (for pharmaceuticals, most commonly from manufacturers' sales to wholesalers and large retail chains), price changes realized by Medicare Part D beneficiaries are out of scope – the PPI does not identify and monitor prices paid by final purchasers such as the elderly at retail or mail order. For the PPI, therefore, implementation of Medicare Part D required no significant changes in the data gathering protocols. Instead, the PPI continued to introduce new branded and generic drugs as supplemental samples into its sample of price quotes on an annual basis.[14]

In contrast to the PPI program, the BLS' CPI program faced a number of serious challenges in adapting its price measurement protocols to the introduction of the transitional Medicare Discount Card and then the launch of the full Medicare Part D program. Because the Centers for Medicare and Medicaid Services ("CMS") website contained a pricing utility set up

explicitly for beneficiaries to determine how the various discount card plans compared to each other in terms of drugs covered and their prices, beginning in October 2004 the CPI flipped a portion of their existing sample – the senior cash discounted portion that had been receiving about a 10% discount – from discounted cash to Medicare discount card, where they recorded an average additional discount of 15% off retail and mail order cash prices; these quotes were then employed in the aggregate index calculations.[15] As of December 2004, the BLS was collecting 1,111 price quotes for prescription drugs.[16] Since CMS ceased supporting the pricing utility which yielded the Medicare Discount Card price quotes in November 2005, for November and December 2005 the BLS estimated these price quotes as being approximately 25% off the full cash price quotes they continued to collect.[17]

To account for the introduction of Medicare Part D in January 2006, the BLS CPI program employed a variant of the directed substitution rule by which the product characteristics of the new item were already known and determined (rather than going through the entire disaggregation process). In particular, the CPI recorded the price changes that occurred for the same prescription as it switched from being paid with a Medicare approved discount card (December 2005) to the full Medicare Part D benefit price (January 2006). The latter was calculated by taking quotes from a single nationally offered private prescription drug benefit plan that conveniently allowed direct pricing via an online pricing utility.[18] In cases where the national Part D plan only offered the generic equivalent of a brand drug covered by the discount card plan, the CPI recorded the price change between the brand discount card and the generic Part D price. Note that only discount card to Part D changes were captured by the BLS CPI, and that the quoted changes are those based on a single national plan.[19] In particular, the CPI program has not attempted to capture price quotes of formerly uninsured cash or partly insured

customers who subsequently obtained Part D coverage. Similarly, because direct substitution procedures were employed, any switches from retail to mail order that occurred because of Part D private prescription drug plan benefit design were also not captured by the CPI.

Because a portion of the Medicare approved discount cards that came into the CPI sample in 2004 were rotated out of the sample and were not adequately replaced through rotation, BLS augmented its Medicare approved discount card sample to match CMS' estimate that approximately 3.7% of the US population had been issued such cards. This was accomplished by the BLS randomly assigning Part D quotes to their existing sample. As a result, the Part D sample may not mirror a market snapshot that would have emerged had the BLS initiated the Part D drugs from the pharmacy based on their traditional last-20 prescription method. We note in passing that in the future when it initiates a new sample frame, the BLS will finally be able to measure and compare prescription drug prices paid by the elderly through Part D with purchase prices paid by the non-elderly.

Coincidentally, the BLS CPI program has been wrestling with how to incorporate prescription-only to over-the-counter ("Rx to OTC") switches into its medical care CPI, which includes both types of drugs. Two very prominent recent Rx to OTC switches have involved the Claritin for the treatment of allergies (approved November 27, 2002) and Prilosec OTC for the treatment of frequent heartburn (approved June 20, 2003).[20] Conversations with BLS CPI personnel reveal that when there is an Rx to OTC switch, the BLS treats the initial price of the OTC variant as the final price of the Rx version, and then treats subsequent OTC price changes as only affecting the OTC price index. Note that since the BLS CPI is based on a Laspeyres aggregation framework, the Laspeyres aggregate of an Rx price index and an OTC price index is numerically equivalent to a Laspeyres index aggregated simultaneously over all Rx and OTC

products.[21] A related pilot project is underway at the BLS CPI program involving the creation of separate brand and generic CPIs for prescription pharmaceuticals. Currently the BLS only publishes an aggregate of prescription pharmaceuticals.

C. Expectations Regarding Impact of Medicare Part D on BLS' Price Measures

As several of us authors have written elsewhere, we believe the BLS faces enormous challenges in reliably measuring price inflation for health care goods and services, including prescription drugs.[22] The introduction of Medicare Part D benefits likely increases these challenges and difficulties for the BLS. What are reasonable expectations regarding how the introduction of Medicare Part D impacted price inflation as measured and reported by the pharmaceutical CPI and PPI? Four points are worth noting.

First, prior to implementation of Medicare Part D, about 25% of the elderly had been paying cash prices for prescription drugs. As of January 1, 2006, these individuals became eligible to enroll in Medicare Part D and benefit from lower prices negotiated on their behalf by private prescription drug plans.[23] While undoubtedly not all of those eligible actually enrolled, as we have seen, the price declines experienced by those individuals who did enroll will not have been captured by the CPI. In this sense, to the extent such transaction types are not being captured, growth in the prescription drug CPI has been overstated. Looking to the future, although some Medicare Part D transactions will have been uncovered by the Consumer Expenditure Survey ("CES") data (none from 2005, but presumably those from the 2006 CES), the resulting new CES weights will be set as of December 2007 for use only beginning with the January 2008 CPI.

Second, we expect the introduction of new or additional insurance to increase demand, due to moral hazard. Danzon and Pauly have estimated that between 25% and 50% of the total

growth in U.S. prescription drug spending between 1987 and 1996 can be attributed to increased drug insurance coverage by employers and Medicaid over that time period.[24] For branded products having patent exclusivity and constant marginal costs, basic microeconomic theory predicts that as a result of the moral hazard-induced increase in demand, prices will likely rise (or, equivalently, rebates will decrease). Whether price increases occur on or after the time of the implementation of Medicare Part D, or in anticipation of it, depends on numerous factors beyond the scope of this paper. In any case, we expect pharmaceutical PPIs to increase as a consequence of the passage and implementation of the Medicare Modernization Act of 2003.

Third, as noted above, switching dual eligibles from Medicaid coverage which entailed "most favored nation" pricing to Medicare private prescription drug plans ("PDPs") not subject to the Medicaid mandatory rebates, provided the PDPs with less bargaining power than the state and federal Medicaid purchasers had previously been able to exercise. Recall that it is estimated that 29% of the Medicare Part D enrollees had previously been dual eligibles.[25] To the extent this has occurred, we might expect prices of drugs disproportionately used by the previous dual eligibles to increase more rapidly than other drugs. Below we comment on the therapeutic drug classes that are likely to be more intensively utilized by previous dual eligibles.

Fourth and finally, in their negotiations with CMS regarding formulary design, the PDPs were constrained by CMS to include a minimal number of (often at least two) drugs with preferred status in each therapeutic class, and in some cases such as the antidepressants, all drugs.[26] Since payors' buying power relative to manufacturers stems in large part from payors' ability to either exclude drugs entirely from their formulary or at least banish them to the third tier having the highest copayment, this broad formulary policy constrained the buying power of the PDPs, and likely has led to reduced rebates and/or increased prices.

Together these four considerations suggest that we should expect passage of and then implementation of Medicare Part D legislation to be associated with reduced rebates/increased pharmaceutical prices, particularly in the pharmaceutical PPIs. Given the 30-month time span between the June 2003 initial passage of the legislation and its full implementation in January 2006, however, it is unclear what to expect in terms of the timing of such price increases. Finally, we expect PPIs in therapeutic classes including drugs disproportionately used by previous dual eligibles to increase more rapidly than PPIs for drugs in other classes.

IV. Results: Trends in BLS Measures of Pharmaceutical CPI and PPI Price Inflation

We now move on to a discussion of trends in BLS' measured price inflation, with a particular focus on dates surrounding developments in Medicare coverage of prescription pharmaceuticals. We begin with the CPI, and focus on five time periods over the last ten years: (i) January 1996 – January 2000 – early history; (ii) January 2000 – June 2003, the latter being the month in which initial House and Senate versions of the Medicare Prescription Drug, Imprrovement and Modernization Act were passed. We then divide the following 30-month time period until the January 1, 2006 implementation of Medicare Part D into two equal 15-month time intervals; (iii) June 2003 – September 2004; (iv) September 2004 – December 2005; and finally, (v) December 2005 – October 2006, the time period following implementation of the Medicare Part D program. For each of these time periods, we compute annualized average growth rates ("AAGRs").

A. Results: The CPIs

As we noted earlier, the set of price quotes interpreted as reflecting Medicare Part D transactions is based in part on the BLS flipping Medicare discount card quotes on to Medicare Part D based on online price quotes from a single national private prescription drug plan website,

and part on randomly taking certain existing price quotes and converting them to a Part D comparison over time. The latter set of quotes may, however, have not originally been those of elderly individuals, and thus the composition of prescriptions in the Part D subsample may not be representative of that for the overall elderly population enrolled in Part D.

In Table 1 below we compare the distribution of prescriptions by therapeutic drug class in the overall sample of prescription drug CPI quotes with that in the Part D subsample, over the January – October 2006 time frame. There are six therapeutic classes in which there are zero Part D quotes – except for anesthetics (at 9.67%) the prescription shares of these classes in the

TABLE 1

Distribution of Prescriptions by Therapeutic Class in the Overall and Medicare Part D Samples, January – October 2006

Therapeutic Class	Prescription Share in Overall Sample	Prescription Share in Part D Sample
Analgesics	8.10%	14.63%
Anesthetics	9.67	0.00
Antidotes	1.16	0.00
Antimicrobials	9.88	9.76
Cardiovascular	14.30	17.07
Central Nervous System	11.99	7.32
Gastrointestinals	5.26	4.88
Hematologics	1.79	2.44
Hormone	10.20	9.76
Immunologics	0.11	0.00
Metabolics/Nutrients	9.57	14.63
Neurologics	3.47	4.88
Oncolytics	0.32	0.00
Ophthalmics	1.47	0.00
Otics	0.21	0.00
Respiratory Tract	9.04	9.76
Skin/Mucous Membrane	2.00	2.44
Unclassified/Misc	1.47	2.44
TOTALS	100.01%	100.01%

overall sample are quite small, and together the six zero share Part D classes account for 12.94% of the overall sample prescriptions. Not surprisingly, in the cardiovascular and metabolics/nutrients classes the elderly prescription share is considerably larger than in the overall sample; in contrast, for central nervous system and analgesics the elderly prescription share is smaller than in the overall sample.

AAGRs of various CPI indexes are presented in Table 2, over the five time intervals discussed above. In the first two rows we provide AAGRs of the all items-urban CPI, and of the experimental or elderly CPI ("E-CPI") for all items. The overall E-CPI grows slightly more rapidly than the all items CPI, with the differential ranging from about 0.10% to 0.22%, and having no distinct time trend. Previous literature has attributed this differential to the larger share of medical care expenditures for seniors, along with above-average inflation for medical care.

TABLE 2

Annualized Average Growth Rates of Alternative Consumer Price Indexes (Percent)

Time Period / **CPI Index**	**Jan. 1996-Jan. 2000**	**Jan. 2000-June 2003**	**Jun. 2003-Sep. 2004**	**Sep. 2004 - Dec. 2005**	**Dec. 2005-Oct. 2006**
All Items – Urban	2.254%	2.446%	2.691%	2.896%	3.011%
E-CPI – All Items -- Urban	2.404	2.674	2.910	3.003	3.234
Medical Care	3.206	4.324	4.297	4.103	3.996
E-CPI – Medical Care	3.158	4.468	4.380	3.893	3.798
Medical Care Services	3.201	4.675	4.821	4.498	4.225
Medical Care Commodities	3.157	3.142	2.677	2.913	3.128
Prescription Drugs	4.132	4.254	3.602	3.751	4.062

In the next two rows of Table 2 we show AAGRs for the overall medical care CPI, and the overall medical care E-CPI, which differ to the extent that the elderly and non-elderly shares of the components (medical care commodities, medical care services, hospital and related

services, and health insurance) of overall medical care differ, and these components experience varying rates of inflation. In three of the five time intervals, the elderly medical CPI grows slightly less rapidly than that in the overall medical CPI, while the reverse occurs in two time periods. Over the entire ten plus year time frame, the medical E-CPI grows at an AAGR of 3.886%, virtually identical to the medical overall CPI at 3.887%.

Rows five and six provide AAGRs separately for medical care services and medical care commodities; the BLS does not compute experimental elderly CPIs at this level of aggregation, only overall ones. In each of the five time intervals, AAGRs of medical care services (which includes physicians', dental, hospital and nursing home and adult day care services) are greater than those of medical care commodities (prescription and OTC drugs and medical supplies), with the differential since 2000 ranging between 1.0 and 1.7%, and having no distinct trend.

Finally, in the bottom row of Table 2 we provide AAGRs for prescription drugs and medical supplies. Price inflation for prescription drugs has ranged from about 3.6% to 4.3% annualized, and since 2000 it has been less than that for medical care services. There does not appear to be any clear Medicare Part D trend in the rate of prescription drug price inflation – it was 4.25% annually in the 42-month period up to the passage of the initial legislation in June 2003, fell to 3.60% and 3.75% in the two subsequent fifteen month intervals leading up to implementation of Medicare Part D in January 2006, and since then has risen slightly to an AAGR of 4.06%.

In summary, there are no dramatic changes in the AAGRs of various medical care CPIs over the last ten years, and in particular, no sharp changes seem to have taken place in the prescription drug CPI as Medicare Part D legislation was passed and then implemented.

B. Results: The PPIs

We now turn to a consideration of PPIs for pharmaceuticals. Recall that the PPI monitors the price received by the manufacturer (net of discounts and prompt payment price reductions) from sales to the first point in the distribution chain, which for pharmaceuticals is usually either wholesalers or large retail chains. Participation by manufacturers in reporting to the BLS is voluntary; participation rates have been around 65%. Although considerable pharmaceutical manufacturing takes place in Puerto Rico, from the vantage of the BLS' PPI program, Puerto Rico is not part of the U.S.[27]

The BLS' PPI for pharmaceuticals includes both Rx and OTC products. While Medicaid purchases are explicitly out of scope for the CPI (since they are government purchases), for the PPI the identity of the ultimate consumer is irrelevant, and thus the PPI will incorporate prices paid by, among others, Medicaid purchasers (state governments and the CMS). In principle the pharmaceutical PPI also tracks changes in prices that occurred when Medicare-Medicaid dual eligibles switched to the Medicare Part D program in January 2006, although the types of transactions are defined quite narrowly, and at best changes in weights occur only at annual intervals.

We report AAGRs for various pharmaceutical PPIs in Table 3 for five time intervals: (i) June 2001 – June 2003 (since some price series did not begin until June 2001); (ii) June 2003 – September 2004 (the first fifteen months after initial passage of the Medicare Part D legislation); (iii) September 2004 – December 2005 (the final fifteen months before implementation of Medicare Part D in January 2006); (iv) December 2005 – October 2006 (to monitor changes associated with implementation of Medicare Part D); and (v) January 2000 – October 2006 (for some price series, data from the beginning of this decade).

TABLE 3

Annualized Average Growth Rates of Alternative Producer Price Indexes (Percent)

Time Period / **PPI Index**	**Jun 2001 through Jun 2003**	**Jun 2003 through Sep 2004**	**Sept 2004 through Dec 2005**	**Dec 2005 through Oct 2006**	**Jan 2000 through Oct 2006**
All Pharmaceuticals PPI	4.229%	4.379%	5.418%	4.107%	4.126%
Analgesics – Rx	3.491	3.592	1.357	7.716	4.673
Antibiotics – Broad and Medium Spectrum	3.306	5.311	5.350	4.958	4.744
Anticoagulants	2.048	4.701	0.220	0.110	-5.537
Antispasmodic/Antisecretory	3.753	3.426	22.839	10.807	7.981
Other Digestive or Genito-urinary Preps	3.730	2.742	2.436	4.937	na
Bronchial Therapy	6.226	4.104	1.938	-1.097	3.563
Other Rx Respiratory Preparations	7.981	6.196	6.942	4.671	na
Cancer Therapy Products	5.455	0.297	3.708	0.349	4.105
Other Neoplasms, Endocrine System and Metabolic Diseases Including Hormones	10.920	7.294	11.057	8.905	8.751
Cardiovascular	3.953	4.603	4.039	3.038	3.744
ACE Inhibitors	1.784	1.695	0.378	0.452	Na
Other Cardiovascular	5.736	6.319	6.901	4.959	na
Insulin/Antidiabetes	6.087	9.467	6.989	-0.588	5.708
Multivitamins – Rx & OTC	0.799	0.808	-0.200	2.261	1.347
Other Rx Vitamins and Nutrients	3.875	2.808	3.281	2.896	na
Psychotherapeutics	5.789	6.128	8.689	8.000	5.813
Antidepressants	10.990	6.255	14.588	9.683	10.037
Other Psychotropics, including Tranquilizers	2.810	6.010	3.851	6.477	na
Other Central Nervous System And Sense Organs	-5.132	5.737	5.762	3.142	na
Skin Rx Preparations	4.186	13.315	3.971	0.944	na

na = not applicable, since BLS series begins in June 2001

The first row of entries in Table 3 indicates that the overall pharmaceutical PPI has grown at about 4.1% annually since 2000, with slightly larger annual growth at 5.4% in the

fifteen months leading up to implementation of Medicare Part D;[28] since then growth has returned to about 4.1%. There is considerable heterogeneity in AAGRs, both across time intervals and among therapeutic classes. Prices of prescription analgesics (pain medicines), for example, only grew at a 1.4% annual rate in the fifteen months leading up to implementation of Medicare Part D, but then grew at a much larger 7.7% annual rate following its implementation.[29] By contrast, prices of anticoagulants grew at a 4.7% annual rate in between June 2003 and September 2004, but since then have grown at 0.1 – 0.2% annually.[30]

The antispasmodic/antisecretory class includes drugs for the treatment of heartburn (such as the H_2-antagonists and proton pump inhibitors – brands like Zantac, Prilosec and Nexium). This category has experienced particularly volatile price growth – averaging around 3.5% annually to September 2004, but then growing at a very high annual rate of 22.8% up through December 2005,[31] and continuing to grow at a 10.8% annual rate since then.[32] In Table 1, this class of drugs would be in the gastrointestinal category, and data there suggest that the prescription drug share of gastrointestinal drugs is approximately the same for the elderly and non-elderly. We know of no data on whether this class of drugs is consumed disproportionately by the previous dual eligibles.

Returning to Table 3, we see that while cancer therapy products (where utilization might be expected to be disproportionate by the elderly, though typically covered by Medicare Part B for many years) had an AAGR of about 4.1% over the entire January 2000 – October 2006 time frame, in the fifteen months leading up to the January 2006 implementation, prices rose at an annual rate of 3.7%, and since then at a considerably smaller rate of 0.3%. By contrast, the class entitled "Other Neoplasms, Endocrine System and Metabolic Diseases, including Hormones" includes a number of antiosteoperosis drugs for postmenopausal women, and thus its utilization

is likely to be disproportionate by the elderly.[33] As seen in Table 3, over the entire January 2000 – October 2006, price growth has been relatively high in this class, averaging 8.8% annually; between September 2004 and December 2005 it increased at an AAGR of 11.1%, and most recently, at an AAGR of 8.9%.

Of particular interest in the context of Medicare-Medicaid dual eligibles are psychotherapeutic drugs, which are used disproportionately by Medicaid beneficiaries.[34] For the entire class of psychotherapeutic drugs, price growth accelerated from about 6% annually between June 2001 and September 2004, to more than 8% annually since then.[35] The next row in Table 3 indicates that this price acceleration was particularly marked in the antidepressant subclass of psychotherapeutic drugs. For antidepressants the AAGR between September 2004 and December 2005 was 14.6%, more than twice that during the previous fifteen months at 6.3%;[36] this AAGR has fallen since implementation of Medicare Part D to a still substantial 9.7%.[37] Somewhat surprisingly, AAGRs are lower albeit still considerable in the sub-class of psychotherapeutics designated as "Other Psychotropics, including Tranquilizers" which includes the second generation antipsychotic drugs for treatment of schizophrenia. Specifically, for this class of drugs prices grew at an AAGR of around 6.0% between June 2003 and September 2004, then grew at a slower annual rate of 3.9% in the fifteen months leading up to implementation of Part D, and since then have grown at an annual rate of 6.5%.

In summary, therefore, although there is considerable heterogeneity over time intervals and among therapeutic classes, there is evidence based on PPI trends suggesting that some prescription drugs likely disproportionately used by the elderly (e.g., the antiosteoporosis drugs for postmenopausal women) and the Medicaid-Medicare dual eligibles that are now covered by Medicare Part D (such as the various types of psychotherapeutic drugs) have experienced very

considerable price growth leading up to and following implementation of the new Medicare Part D benefit. Although at a much higher level of aggregation, this PPI evidence is consistent with preliminary findings from Frank and Newhouse [2006] that is based on more detailed brand data. However, there is also substantial PPI price growth during these time periods for the antispasmodic/antisecretory drugs – drugs that are not likely to be used disproportionately by the elderly. More research will be needed to clarify these early findings.

V. Price Measurement Adjusting for Quality: The Case of Antipsychotic Drugs

A. Background Literature

We now move on to a rather different discussion – that of adjusting prices for quality variations. In earlier work, we have created price indexes for the treatment of acute phase major depressive disorder using MedStat retrospective national medical claims data, in which we defined alternative treatment bundles based on various combinations of psychotherapy and types of psychotropic medications with differing durations. We then convened an expert rating panel of physicians and psychologists who estimated what proportion of patients presenting with certain symptom combinations would be full or partial responders after twelve weeks of treatment. With the logarithm of treatment spending as the dependent variable, we then estimated multivariate regression equations, in which the explanatory variables included indicator variables for patient characteristics, treatment bundle type, year, and the expert panel's rating of the likely responsiveness. Based on 1991 – 1996 data, we found that adjusted for quality in this way, the treatment price index for an episode of major depressive disorder fell slightly over time.[38]

In other earlier work, we employed 1996 – 2001 Florida Medicaid retrospective medical claims data and identified individuals treated for schizophrenia. Schizophrenia is a chronic

illness, typically requiring lifelong but frequently changing treatment. We defined and identified alternative treatment bundles of psychosocial counseling and various classes of antipsychotic medications, based on the schizophrenia Patient Outcomes Research Team ("PORT") treatment recommendations.[39] Primarily due to the composition of treatments changing substantially over time toward more intensive use of second generation antipsychotics and away from psychotherapy, holding treatment quality type and patient characteristics constant over time, we obtained results from multivariate regression analysis implying that the mean treatment costs fell about 5.5% annually between 1994-95 and 1999-2000.[40]

B. Extension of Previous Research: Measuring Appropriateness of Pharmacotherapy

In each of these series of studies – for acute phase major depressive disorder, and ongoing treatment of schizophrenia – we categorized treatment quality into alternative bundles of care involving psychosocial counseling and classes of medications, but did not attempt to quantify whether any of those treatments were medically appropriate. Particularly for a chronic condition such as schizophrenia, treatment costs can be very much affected by the dose and duration of pharmacotherapy. Here we extend our previous line of research and report preliminary results that focus on the appropriateness of the pharmacotherapy received. Because the focus of this paper is on price indexes for medications, we limit our analysis to examining the "price" of prescribing of antipsychotic medications for a chronic and recurring condition, schizophrenia.

We make use of information on dosing of medications and duration of receipt of medication to assess appropriate prescribing and continuity of treatment. Appropriate dose ranges differ based on whether a patient was considered likely to be in either acute versus maintenance phase treatment.

More specifically, an acute outpatient treatment phase was defined as starting on Day 1 of an inpatient mental health hospitalization, and was considered to last for duration of twelve weeks after Day 1 of the last hospitalization. Therefore, if a rehospitalization occurred within twelve weeks of the prior hospitalization, the acute phase was extended beyond the initial twelve weeks. Since only outpatient prescriptions could be tracked (and inpatient days would vary per acute phase), we implemented a "correction" for calculating the pharmacotherapy duration that took into account the varying number of outpatient days within an acute phase.

We defined a maintenance phase treatment as beginning the first day after an acute phase ended, or, if there were no hospitalization (i.e., no acute phase) in a given fiscal year, then the entire year was considered to be maintenance phase treatment. If a hospitalization occurred during the maintenance phase, then a new acute phase was considered to have begun.

Our dosing quality measure begins as a binary variable, taking on the value 1 if dosing is appropriate, and 0 if inappropriate. Appropriate dosage ranges were informed by the Schizophrenia PORT study.[41] Daily dosages per prescription were determined by first calculating the mg dose per tablet/capsulel multiplied by the number of tablets/capsules and then dividing by the days supplied. The average daily dose per medication day was then calculated over each treatment phase. All the older D2 antagonist antipsychotics were converted to chlorpromazine (CPZ) mg equivalents. If more than one antipsychotic was prescribed concomitantly and all could not be translated into CPZ equivalents (i.e., if one was a D2 antagonist and another a second generation antipsychotic, or if both were second generation antipsychotics), then the antipsychotic dosage was considered inappropriate if *any one* was an inappropriate dose. Dosage for persons who received decanoate antipsychotic prescriptions could not be computed, and therefore in those instances only duration was calculated. In Table 4

below we summarize the medication dosages considered appropriate and inappropriate, separately for acute and maintenance phase treatments.

Table 4

Appropriate Dosing for Antipsychotics

	Recommended Daily Dose Range (mg)			
Medication	**Acute Phase**		**Maintenance Phase**	
	Adequate = 1	Inadequate = 0	Adequate = 1	Inadequate = 0
Chlorpromazine Equivalents	≤ 1000	> 1000	≤ 600	> 600
Clozapine	≤ 600	> 600	≤ 600	> 600
Olanzapine	≤ 20	> 20	≤ 20	> 20
Quetiapine	≤ 750	> 750	≤ 450	> 450
Risperidone	≤ 6	> 6	≤ 6	> 6
Ziprasidone	≤ 160	> 160	≤ 160	> 160
Aripiprazole	≤ 30	> 30	≤ 30	> 30

Antipsychotic duration was then determined by calculating the days supplied of antipsychotic medication for sequential prescriptions in a given treatment phase (acute or maintenance). A binary indicator of appropriate continuity of medication was defined as being equal to one if there was no interruption in days supplied of greater than 30 days, else it was zero. For decanoate injections, adequate continuity was defined as having refills within at least eight weeks from the last prescription.

For each observed patient year, the 0-1 dose and continuity variables were weighted by the corresponding relative days in acute vs. maintenance treatment. Hence both the dose and continuity variables can take on continuous (not dichotomous) values between zero and one.

C. Data Sample Cohort and Price Estimation Method

The data cohort consisted of Medicaid enrollees in two counties in Florida, those containing Jacksonville and Orlando, for the five fiscal years between 1996-1997 and 2000-2001. The administrative claims data included inpatient and outpatient procedure codes (both CPT and state Medicaid-specific), and pharmacy data. These administrative claims files provided us with the compendium of inpatient hospitalizations, outpatient treatments, diagnoses, and medications received, as well as the timing of these services/diagnoses. Previous research has found substantial correlation between Medicaid claims-based diagnoses of schizophrenia compared with clinical interviews and chart reviews.[42] Thus, using Medicaid administrative claims to develop a cohort of enrollees with schizophrenia has demonstrated validity.

Medicaid membership files were used to determine the race, gender, Medicaid eligibility category, Supplemental Security Income status, and date of birth. Enrollees who were dually eligible for Medicare and Medicaid were excluded due to concerns that Medicaid administrative claims would not contain complete service and pharmacy utilization records for this sub-population. Schizophrenia diagnosed enrollees who ever received a substance use disorder (SUD) were considered to have a SUD comorbidity. ICD-9 SUD diagnoses that were included were the alcohol and drug psychoses (291, 292) and other alcohol/drug abuse diagnoses with the exception of tobacco and antidepressant abuse (303, 304, 305.0, 305.2-305.7 and 305.9).

To construct the cohort for our analysis that balanced minimizing the false-positive and false-negative rates, we developed the following algorithm. For the purposes of this study, enrollees with at least two schizophrenia diagnoses (inpatient and/or outpatient treatment; ICD-9 codes 295.0-295.9) were considered to have schizophrenia. The following enrollees with only one schizophrenia claim were also included: those for whom the claim represented an inpatient discharge diagnosis, or, those for whom the single claim was an outpatient claim representing at

least 50% of their entire mental health claims (i.e., one out of two mental health claims had a schizophrenia diagnosis). Enrollees ages 18 through 64 who met the above diagnostic criteria were then selected. Enrollees who did not meet our continuous enrollment criteria of per fiscal year – months not enrolled in Medicaid plus months in a Medicaid HMO (for whom utilization data are not available) had to be less than six months – were also excluded.

Given these data, we specified three econometric models, each with the logarithm of annual fiscal year spending on antipsychotic drugs as the dependent variable. In the base case model, we included indicator variables for the fiscal years, race (black, other race, and white being the omitted category), gender (female, male omitted), whether person had substance use disorder (SUD = 1 if so, else zero), and whether individual received Supplemental Security Income benefits for more than half the fiscal year (SSI = 1 if so, else zero). In the second specification, we added an indicator variable designating whether the person was prescribed a second generation antipsychotic medication during the year. Second generation antipsychotics ("SGAs") are generally newer drugs than the older typical antipsychotics, and all but one of the these drugs (clozapine) is still patent-protected. In the final "appropriate prescribing" specification, we add the two measures of appropriate prescribing – dosing and continuity. To account for multiple observations on the same individual, we employ the GEE estimator, clustering on individuals. Our 1996-1997 through 2000-2001 sample consists of 10,829 person years, of which there are 3,412 distinct persons; thus a person was observed for an average of 3.17 years.

D. Empirical Findings

The research reported here is preliminary and incomplete, and additional analyses are underway. However, several striking findings have emerged to date. First, as shown in the first

column of Table 5, over the 1996/1997 through 2000/2001 time period, there has been a modest improvement in the proportion of appropriate dosing of antipsychotics, increasing from 59.5% to 64.6%. Though not shown in this table, the trend in dosing is similar for the first generation and second generation antipsychotics, although the proportions of dosing appropriateness are generally greater for the second generation medications than with the older antipsychotics. Recall that our data end in 2000/2001, and thus it is possible that recent controversies regarding alleged excessive dosing of second generation antipsychotic drugs may represent a more recent phenomenon.[43] Second, regarding appropriate continuity, there has been hardly any change in the proportion appropriate – 74.5% in 1996/1997, and 75.0% in 2000/2001. The continuity time trend was similar for both the newer and older antipsychotic agents, but again the proportions were generally slightly higher for the second generation antipsychotic drugs.

Table 5

Measures of Appropriate Pharmacotherapy and Index of Quality-Adjusted Expenditures on Antipsychotics, by Fiscal Year, Florida Medicaid

	Appropriate Pharmacotherapy		Index of Quality-Adjusted Annual Antipsychotic Expenditures		
Fiscal Year	**% Dose Appropriate**	**% Continuity Appropriate**	**Base Case**	**Add Second Generation Drug Dummy Variable**	**Add Appropriate Prescribing Variables**
1996/1997	59.5%	74.5%	1.000	1.000	1.000
1997/1998	62.1	72.3	1.246	1.121	1.128
1998/1999	60.9	73.8	1.671	1.404	1.408
1999/2000	62.9	73.4	2.265	1.790	1.798
2000/2001	64.6	75.0	2.783	2.092	2.092

Given the relatively modest improvement in appropriate dosing over time and the flat appropriate continuity trend, along with the fact that the proportion of persons receiving second-generation antipsychotics increased from 18.7% in 1996/1997 to 68.1% in 2000/2001, we expect

that the very dramatic increase in antipsychotic drug spending per patient year over time is primarily associated with increases in the proportion of Medicaid persons being prescribed the second generation agents. In Table 6, we present parameter estimates from three multivariate regression models; the corresponding imputed quality-adjusted expenditure (or price) indexes are given in the last three columns of Table 5.

A number of results in Table 6 are noteworthy. First, comparing the second with the first column reveals that the addition of the indicator variable for the second generation antipsychotic medication generates a large positive and statistically significant coefficient estimate; exponentiation of 0.9205 implies that holding other things equal, prescribing a second generation drug increases annual antipsychotic spending on a patient by about 251%. While most of the other coefficient estimates are relatively similar in the first two columns, those on the fiscal year dummies are not; we attribute this to the strong growth over time in the prescribing of second generation agents that we noted above.

Second, comparison of parameter estimates in the last two columns of Table 6 again reveals relative stability in these estimates, but now also for parameters on the fiscal year dummy variables. We interpret this as reflecting the relative absence of any strong trend in the appropriate dose and continuity variables. The positive coefficient estimate on the appropriate continuity indicator variable implies that per person per year expenditures will increase with higher levels of appropriate continuity, an expected result. Even more interesting, however, is the negative coefficient estimate on the appropriate dosing proportion; as this proportion increases, expenditures on antipsychotics per patient year decrease. This reflects the fact that inappropriate dosing by definition here involves too high a dose, and the fact that these antipsychotics generally

Table 6

Parameter Estimates of Antipsychotic Expenditure Models
GEE Standard Errors Clustered by Individual in Parentheses
Florida Medicaid Data, 1996/1997 – 2000/2001

	Alternative Model Specification Estimates		
Variable	**Base Case Model**	**Add Second Generation Dummy Variable**	**Add Appropriate Prescribing Variables**
Constant	6.0973*** (0.132)	5.4060*** (0.131)	5.4530*** (0.132)
FY 1997/1998	0.2197*** (0.034)	0.1140*** (0.036)	0.1140*** (0.036)
FY 1998/1999	0.5137*** (0.038)	0.3390*** (0.040)	0.3390*** (0.030)
FY 1999/2000	0.8174*** (0.040)	0.5824*** (0.041)	0.5824*** (0.041)
FY 2000/2001	1.0236*** (0.040)	0.7381*** (0.041)	0.7380*** (0.041)
Black	-0.4828*** (0.048)	-0.3759*** (0.045)	-0.3477*** (0.045)
Other Race	-0.3517*** (0.055)	-0.3042*** (0.053)	-0.2775*** (0.052)
Age	-0.0060*** (0.002)	-0.0014 (0.002)	-0.0011 (0.002)
SSI Recipient	-0.0533 (0.106)	0.0115 (0.100)	0.0258 (0.096)
SUD Diagnosis	-0.3249*** (0.045)	-0.4243*** (0.044)	-0.4286*** (0.044)
Female	-0.0108 (0.0432)	-0.0713* (0.041)	-0.0512 (0.040
Atypical Antipsychotic		0.9205*** (0.040)	0.8970*** (0.040)

Appropriate Continuity			0.2410*** (0.033)
Appropriate Dose			-0.3588*** (0.038)
Note: ***, **, and * denote statistical significance at p-values ≤ 0.001, 0.01 and 0.05 respectively.			

cost more as dosage strength increases. This finding represents a rare case where improved quality of care is clearly associated with reduced health care spending. In terms of the other regressors, coefficient estimates on the Black and Other Race indicator variables are negative and significant, as is that on the SUD substance use disorder indicator variable. Coefficient estimates on age, Supplemental Social Insurance ("SSI") recipient, and Female are generally insignificant.

Finally, in terms of an index of quality-adjusted expenditures per patient year on antipsychotic drugs (which corresponds roughly to a partial price index for the ongoing treatment of schizophrenia), in the final three columns of Table 5 we exponentiate the fiscal year dummy variable coefficient estimates in the last column of Table 6, and index them to 1.000 in the 1996/1997 base year. As is seen in Table 5, growth in this price index changes dramatically once one includes an indicator variable for receipt of a second generation antipsychotic prescription into the multivariate regression, sharply reducing the level of the price index in 2000/2001 from 2.783 to 2.092, and thereby decreasing the implied AAGR from 29.2% to 20.3%. Finally, even though additional inclusion of the appropriate continuity and dosing variables significantly improves goodness of fit, since these pharmacotherapy quality variables are essentially uncorrelated with the fiscal year indicator variables, the quality-adjusted price (expenditures on antipsychotic medicines per patient year) indexes are virtually unchanged with or without these pharmacotherapy quality variables included.

VI. Concluding Remarks

In this paper we have focused on pricing impacts from passage and implementation of the landmark Medicare Part D legislation, both for consumers and producers. Measuring prices in a post-Medicare Part D era presented essentially no new issues and requirements for the BLS' Producer Price Index program (it is essentially unconcerned with identification of the final consumer), but measuring and monitoring the price impacts on consumers presented a number of new and significant challenges to the Consumer Price Index program. Our tentative conclusion is that only some of the benefits of Medicare Part D in terms of lower prices to consumers are being captured by BLS CPI price collection methods, although this may improve when new 2006 Consumer Expenditure Survey weights are incorporated into the reweighted CPI in January 2008.

In terms of measured impacts to date, there are no dramatic changes in the AAGRs of various medical care CPIs over the last ten years, and in particular, no sharp changes seem to have taken place in growth of the prescription drug CPI as Medicare Part D legislation was passed and then implemented.

For the pharmaceutical PPIs, however, although there is considerable heterogeneity over time intervals and among therapeutic classes, there is evidence suggesting that some prescription drugs likely disproportionately used by the elderly (e.g., the antiosteoporosis drugs for postmenopausal women) and the Medicaid-Medicare dual eligibles that are now covered by Medicare Part D (such as the various types of psychotherapeutic drugs) have experienced very considerable price growth leading up to and following implementation of the new Medicare Part D benefit. Although at a much higher level of aggregation, this PPI evidence is consistent with preliminary findings from Frank and Newhouse [2006] that is based on more detailed brand data.

However, there is also substantial PPI price growth during these time periods for the antispasmodic/antisecretory drugs – drugs that are not likely to be used disproportionately by the elderly. More research will be needed to clarify these early findings.

Antipsychotic agents are especially important in assessing the impact of implementation of Medicare Part D because these drugs are disproportionately used by people whose drug purchasing was switched from Medicaid to Medicare under the MMA. Therefore understanding the most precise approach to characterizing "producer price indexes" for these drugs will serve more complete future assessments of the impact of Part D on drug prices.

We have presented new research findings on changes in spending by Florida Medicaid on antipsychotic drugs over the 1996/1997 to 2000/2001 fiscal year time period, and find that the spending increases are associated primarily with increases in the use of second generation antipsychotics, whose penetration among those treated for schizophrenia increased from about 19% to 68% over that five year time frame. Based on findings from the PORT study and its treatment recommendations, we have quantified the extent to which Florida beneficiaries were being prescribed appropriate doses of antipsychotic drugs, as well as the extent to which the continuity of treatment was also appropriate. We find that while the proportion of individuals receiving appropriate dosing increased modestly from 59.5% in 1996/1997 to 64.5% in 2000/2001, and that this proportion was consistently greater for the newer antipsychotics. The proportion of individuals receiving appropriate duration of antipsychotic treatment remained essentially unchanged at 75% over this five year time frame.

We estimated multivariate hedonic-like regressions with the logarithm of annual expenditures on antipsychotic drugs as the dependent variables, and with year dummies and various demographic and patient-specific variables as regressors. The pattern of yearly

coefficients was very sensitive to whether a second generation antipsychotic dummy variable was included as a regressor, reflecting the strong time trend in the proportion of individuals prescribed this class of drug. Although coefficients on the appropriate continuity and appropriate dosing treatment quality variables were statistically very significant, because of the relative absence of any time trend in these quality measures, quality-adjusted price (expenditure) indexes were essentially unaffected by their inclusion or exclusion into the underlying regression specifications. In future research it will be important to assess whether there are any spillover impacts from appropriate antipsychotic treatment quality variations on other drug costs, and on non-drug medical costs, such as those involving psychosocial counseling and physical health expenditures.

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FOOTNOTES

[1] See United States Senate Finance Committee [1996].
[2] Berndt, Cockburn, Cocks, Epstein and Griliches [1998a,b].
[3] Rice and Horowitz [1967], p. 28. This excerpt is based on U.S. Department of Health, Education and Welfare [1967]. Rice and Horowitz (p. 25) report that the December 1965 – December 1966 AAGRs ranged from 2.5% for cholecystectomy to 6.9% for prostatectomy, while the combined index for physicians' fees regularly priced for the CPI rose 7.8%.
[4] Berndt, Cockburn, Cocks, Epstein and Griliches [1998a,b].
[5] United States Senate Finance Committee [1996].
[6] Moulton and Stewart [1997], p. 21.
[7] In this context it is worth noting that because of Medicare reimbursement policies to physicians and hospitals, the elderly purchase much of their health care under administered prices.
[8] Wikipedia [2006].
[9] Cubanski and Neuman [2006].
[10] United States Department of Labor, Bureau of Labor Statistics [2006].
[11] Cubanski and Neuman [2006], Exhibit 5.
[12] See Morton [1997] and Frank [2001] for details.
[13] Frank and Newhouse [2006].
[14] For a discussion of supplemental sampling and other details on the PPI, see Berndt, Griliches and Rosett [1993], and Berndt, Cutler, Frank, Griliches, Newhouse and Triplett [2000,2001]. We have benefited from correspondence with Frank Congelio in the BLS' PPI program regarding recent supplemental sample introductions.
[15] United States Department of Labor, Bureau of Labor Statistics [2006].
[16] United States Department of Labor, Bureau of Labor Statistics [2005].
[17] We are not aware of any empirical analyses substantiating the average 25% discount off of full cash price for these consumers.
[18] Cubanski and Neuman [2006] report that ten organizations captured 72% of the Part D enrollment, primarily in low premium plans and those associated with name recognition. Two organizations --- UHC-Pacific (United) and Humana dominated, together accounting for 45% of Part D enrollment.
[19] We are unaware how the CPI program deals with varying copayments, deductibles, and rebates.
[20] U.S. Food and Drug Administration [2003,2002].
[21] This assumes of course that the OTC and Rx weights are adjusted appropriately in month 2 after the switch.
[22] See, for example, Berndt, Cutler, Frank, Griliches, Newhouse and Triplett [2000,2001].
[23] Frank and Newhouse [2006].
[24] Danzon and Pauly [2002].
[25] Cubanski and Neuman [2006], Exhibit 5.
[26] Huskamp, Rosenthal, Frank and Newhouse [2000].
[27] For further discussion on details regarding the pharmaceutical PPI, see Berndt, Grilliches and Rosett [1993].
[28] About one third of this inflation occurred between June and July 2005.
[29] About half of this increase occurred between June and July 2006.
[30] A 41% decline in this PPI occurred between December 2000 and January 2001. BLS officials indicate this was due to entry by generic drugs.
[31] About half of this increase occurred between April and May 2005.
[32] About three quarters of this increase took place between June and July 2006.
[33] From Table 1, we see that the class of "Hormones" has roughly an equal share of around 10% for both the elderly and the non-elderly. The hormonal class also includes contraceptives, however, which are not generally used by the elderly. Clearly, the hormone class is heterogeneous.
[34] See, for example, Newhouse [2004], Duggan [2005] and Frank, Berndt, Busch and Lehman [2004].
[35] Almost all of the September 2004 – December 2005 inflation took place between June and July 2005.
[36] The PPI for antidepressants increased by 19.1% between June and July 2005.
[37] The antidepressant price growth is somewhat surprising. Prozac, the leading selling antidepressant, lost patent protection and experienced generic entry beginning August 2, 2001; yet from Table 3 we see that between June 2001 – June 2003 prices in this sub-class grew at an AAGR of almost 11%. Similarly, the branded antidepressant Zoloft lost patent protection and experienced generic entry beginning June 30, 2006.

[38] Studies in this vein include Berndt, Bir, Busch, Frank and Normand [2004], Berndt, Busch and Frank [2001], Busch, Berndt and Frank [2001], Frank, Berndt and Busch [1999], and Berndt, Busch and Frank [1998].
[39] Lehman and Steinwachs [1998]. For further details, see Frank, Berndt, Busch and Lehman [2004].
[40] Frank, Berndt, Busch and Lehman [2004], and Berndt
[41] Lehman and Steinwachs [1998]. Aripiprazole (brand name Abilify) was not on the market when the PORT study was conducted. Appropriate prescribing ranges were constructed using information in the product labeling package insert.
[42] See, for example, Lurie, Popkin, Dysken, Moscovice and Finch [1992].
[43] See, for example, Lieberman, Stroup, McEvoy et al. [2005], Freedman, Carpenter, Davis et al. [2006], and Rosenheck, Leslie, Sindelar et al. [2006].