Drug Use Patterns in Severely Mentally Ill Medicare Beneficiaries: Impact of Discontinuities in Drug Coverage

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Objective. To describe the extent of drug coverage among severely mentally ill Medicare beneficiaries and to determine whether and to what extent discontinuities in prescription drug coverage influence the use of medications used to treat serious mental health conditions.

Data Source. 1997–2001 Medicare Current Beneficiary Surveys.

Study Design. We use a zero-inflated negative binomial model to estimate: (1) the probability of not receiving any mental health drug and (2) the number of medications received, adjusting for age, race, income, census region, health status, and comorbidity. Severe mental illness is defined using inpatient and outpatient claims with ICD-9 codes of schizophrenia, other psychotic disorders, bipolar disorders, and major depression. Mental health medications include antidepressants, antipsychotics, mood stabilizers, anxiolytic/sedative-hypnotics, and stimulants. Prescription drug coverage is assessed as full coverage (0 percent discontinuities), no coverage (100 percent discontinuities), or as discontinuous coverage, measured as 1–25, 26–50, and 51–99 percent of time without coverage.

Data Collection/Extraction Methods. We constructed three 3-year longitudinal cohorts of severely mentally ill Medicare beneficiaries residing in the community ($n = 901$).

Principal Findings. Severely mentally ill Medicare beneficiaries with drug coverage discontinuities are more likely than their continuously insured peers not to receive medications used to treat mental health disorders, with the most significant impact seen in the probability of receiving any psychiatric medications. Analysis of two therapeutic classes—antidepressants and antipsychotics—revealed varying impacts of drug gaps on both probability of any drug use, as well as number of medications received among users.

Conclusions. Severely mentally ill Medicare beneficiaries may be particularly vulnerable to the Medicare Part D drug benefit design and, as such, warrant close evaluation and monitoring to insure adequate access to and utilization of medications used to manage mental illness.

Key Words. Drug coverage, mental health, prescription drugs, Medicare, access

Although implementation of the new Part D drug benefit is beneficial for Medicare beneficiaries previously without drug coverage, there is increasing concern that the benefit's "doughnut hole" design may result in reduced access to prescribed medicines (Stuart, Simoni-Wastila, and Chauncey 2005; Donohue 2006). Such discontinuities in drug coverage may be particularly detrimental to older and disabled individuals with chronic conditions, such as serious mental illnesses, for whom prescription drugs represent a necessary, even life-saving, treatment modality. Indeed, an analysis conducted using the Medicare Current Beneficiary Survey (MCBS) found that discontinuities in prescription drug coverage resulted in sizable reductions in drug use and spending (Stuart, Simoni-Wastila, and Chauncey 2005). Furthermore, these reductions in drug use and spending were disproportionately magnified in those beneficiaries experiencing chronic medical conditions, notably chronic obstructive pulmonary disease, diabetes, and mental illness.

A growing body of literature demonstrates that older adults who have no prescription drug coverage utilize fewer drugs (Stuart and Coulson 1993; Adams, Soumerai, and Ross-Degnan 2001; Federman et al. 2001; Poisal and Murray 2001; Steinman, Sands, and Covinsky 2001; Mojtabai and Olfson 2003; Goldman et al. 2004; Piette, Heisler, and Wagner 2004). There also is a body of research documenting that prescription drug use and spending decline as individuals bear greater out-of-pocket expenses in copayments and deductibles (Cox et al. 2001; Cox and Henderson 2002; Saver et al. 2004), although little evidence relates to specific groups of elders or disabled, such as the severely mentally ill, who may be more vulnerable to such cost-sharing provisions.

Despite this broad literature base, there is scant empirical evidence on the extent to which discontinuities in drug coverage affect drug use and spending among Medicare beneficiaries. In two survey-based analyses of Medicare HMO enrollees in plans with annual prescription benefit caps between \$200 and \$1,200, researchers demonstrated that many beneficiaries reduced their medication use after they exceeded the cap (Rector and Venus

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2004; Tseng et al. 2004). A third study found aged Medicare beneficiaries suffering from common chronic conditions, including mental health disorders, experienced longer gaps in prescription drug coverage and, subsequently, experienced sizeable reductions in medication use and spending, relative to individuals with full prescription drug coverage (Stuart, Simoni-Wastila, and Chauncey 2005). Other research has established individuals with chronic conditions tend to be price sensitive in their demand for pharmacologic therapy (Soumerai et al. 1994; Blustein 2000; Stuart et al. 2004) and, therefore, may represent the individuals most likely to be affected by discontinuities in drug coverage, such as the Part D benefit “doughnut hole” design.

In this study, we examine how discontinuities in drug coverage impact the use of medications used to treat psychiatric conditions by severely mentally ill Medicare beneficiaries. Severe mental illness (SMI) was chosen for several reasons: the importance of pharmacologic treatment modalities in treatment of mental disorders, the detrimental impact of mental illness on patients’ quality of life and health, the relatively common prevalence of mental disorders among Medicare beneficiaries, and because prior research has demonstrated individuals with one or more mental conditions are disproportionately impacted by drug coverage gaps (Stuart, Simoni-Wastila, and Chauncey 2005). We have two study objectives: (1) to describe the extent of drug coverage possessed by severely mentally ill Medicare beneficiaries before Part D; and (2) determine whether and to what extent discontinuities in prescription drug coverage influence the use of prescription medications necessary in the treatment of serious mental health conditions.

METHODS

Data

This study uses data from the 1997–2001 MCBS Cost and Use files. The MCBS is a nationally representative longitudinal survey of Medicare beneficiaries conducted by the Centers for Medicare and Medicaid Services (CMS) (Center for Medicaid and Medicare Services 2007). The survey collects extensive information on individual demographic characteristics, health and functional status, medical and prescription drug insurance supplements (including plan begin and end dates which are used to operationalize prescription drug coverage gaps), and annual utilization and expenditures for all health services, including prescriptions. Administrative data, including Medicaid and Medicare enrollment and all Part A and Part B Medicare billing records, augment the survey data.

Study Sample

We constructed a cohort of community-dwelling MCBS respondents with SMI and followed each person for up to 3 years in order to provide an ample time frame for capturing evidence of gaps in prescription drug coverage, including multiple gaps. We identified individuals with SMI based on the presence of the following diagnoses codes using Part A and Part B Medicare claims: schizophrenia and other psychotic disorders (ICD-9 294.xx, 295.xx, 297.xx, 298.xx, and 299.xx); manic and bipolar disorders (296.0, 296.1, 296.4–296.9); and major depressive disorder (296.2, 296.3) (Buck et al. 2004). For inclusion into the sample, individuals had to have one or more SMI diagnoses in the baseline year and at least one other diagnosis during any subsequent year. We excluded beneficiaries enrolled in Medicare HMOs (Medicare+Choice plans) because they lacked the diagnostic information required to identify SMI. We also excluded residents in long-term care facilities because there are no available data on prescription drug use and respondents with missing survey rounds. Analyses are adjusted to correct for decedents' follow-up time in the sample for those who died. Application of these criteria resulted in a total sample of 901 Medicare beneficiaries with SMI.

Variables

The dependent variable of total mental health prescription drug fills was measured as total drug counts during the 3-year study period. In the MCBS, prescription fills are measured as prescription medication events (PMEs). PME fills of greater than 30 days were standardized into 30-day equivalents. We examined total mental health drug fills, as well as those for antipsychotics and antidepressants. These two drug classes represent particularly important pharmacologic treatments for the severely mentally ill.

Mental health drugs included: central nervous system stimulants (e.g., methylphenidate, pemoline, provigil); anxiolytic/sedative–hypnotics which includes, benzodiazepines (e.g., diazepam, alprazolam), nonbenzodiazepines (e.g., buspirone), barbiturates (e.g., secobarbital, amobarbital), and nonbarbiturates (e.g., zolpidem, chloral hydrate, glutethemide); antimanic drugs (i.e., lithium); select anticonvulsants with mood-stabilizing properties (e.g., carbamazepine, clonazepam, lamotrigine, topiramate, valproic acid/valproate); antidepressants; and antipsychotics. The antidepressant class included second-generation antidepressants (includes selective serotonin reuptake inhibitors, selective norepinephrine reuptake inhibitors, and α -2 receptor antagonists) and traditional antidepressants (tricyclic antidepressants,

monoamine oxidase inhibitors, heterocyclic antidepressants). Similarly, in defining the antipsychotic class we included atypical antipsychotics (e.g., clozapine, olanzapine, risperidone, quetiapine, ziprasidone) and typical antipsychotic agents (e.g., haloperidol, chlorpromazine, perphenazine, thiorazine, thiothixene).

The independent measure of interest—discontinuities in drug coverage—is captured through a series of monthly flags for prescription drug coverage based on survey self-reports. Based on prior work, we knew that shorter drug coverage discontinuities impacted drug use (Stuart, Simoni-Wastila, and Chauncey 2005); thus, we categorized measures of drug discontinuities into: continuous, drug coverage (i.e., 0 percent time spent in coverage gaps) which serves as the reference measure, and for noncontinuous drug coverage, four distinct levels of coverage were classified; 1–25 percent time spent in coverage gaps; 26–50 percent time spent in coverage gaps; 51–99 percent time spent in coverage gaps; and no drug coverage (100 percent time spent in coverage gaps).

Two secondary independent measures of interest included income and the presence of supplemental health insurance. Self-reported annual income was classified as percentages of federal poverty level (FPL) (<100; 100–150; 151–300; and >300 percent FPL). Income is inflated by 20 percent to account for underreporting (Poissal 2003). Beneficiaries exceeding FPL of 150 percent are not eligible for low-income subsidization (LIS) under the Medicare Modernization Act. Beneficiaries with incomes <150 percent of the FPL may be eligible for LIS if they meet additional restrictions on financial assets. The MCBS does not contain information on beneficiary assets. The stability of supplemental coverage of across the 3 years of the study (or the period in which the respondent was included in the cohort) was examined and was remarkably stable. Therefore, we classified health insurance coverage supplemental to Medicare into four categories: (1) no evidence of any supplemental coverage other than Medicare; (2) continuous Medicaid coverage; (3) continuous non-Medicaid supplemental coverage; and (4) all other combinations of supplemental insurance coverage. The first three measures characterize beneficiaries who experienced only that type of coverage over the cohort period. “Mixed” supplemental coverage represents individuals who had more than one type of supplemental coverage and/or who did not maintain constant coverage over the 3-year study period.

We control for beneficiary demographics, geography, health status, and mortality. Demographic characteristics include age (<65, 65–74, 75, and older), gender, and race (white versus nonwhite, where nonwhite is

characterized by individuals reporting African American, Asian, Hispanic, Native American, and other racial and ethnic status), socioeconomic constructs are measured using variables measuring educational attainment, and income. We assess geographic differences by using census region (Northeast, Midwest, South, and West). Three variables measure health status: self-reported general health status, self-reported mental illness, and a comorbidity index. General health status includes responses of “excellent,” “very good,” “good,” “fair,” and “poor,” which were dichotomized to “good to excellent” and “fair to poor” health. Although our analytic sample is based upon individuals meeting our criterion for SMI using claims-based ICD-9 diagnoses codes, we also include survey-based self-reports of having any mental illness in the past year as an added explanatory variable. To control for comorbidities, we use the diagnostic cost group/hierarchical coexisting condition (DCG/HCC) risk adjuster, which captures the presence of up to 189 medical conditions based on diagnoses recorded on a beneficiary’s Medicare Part A and Part B claims. The DCG/HCC has been extensively validated and is currently used to risk adjust capitation payments to Medicare Advantage plans (Pope, Ellis et al. 2000; Pope, Kautter et al. 2004). We also included as a covariate a series of dummy variables to reflect the first year of the beneficiary’s MCBS survey (1997, 1998, or 1999) to control for the different observation windows in the data set.

Analytic Approach

Frequency distributions and means are used for descriptive analyses. We describe mental health drug utilization by gap status within our entire SMI sample, as well as differentiate by mental health drug users and nondrug users.

For multivariable analysis, we chose a zero-inflated negative binomial model to examine the impact of discontinuities in drug coverage and income on the odds of not receiving any mental health drugs and the number of mental health drugs received, adjusting for covariates. This model specification was selected for a number of reasons. First, our dependent variable is a count of prescriptions, and counts are generated by a Poisson process. Second, we used a negative binomial model to account for overdispersion. Finally, we selected a zero-inflated count model to correct for the high proportion of zeros in the dependent variable (beneficiaries who had no prescriptions for mental health drugs). The zero-inflated negative binomial model assumes two latent groups. Individuals in one group never have a prescription for a mental health drug (i.e., always have a count of zero with a probability of 1), while individuals

in the other group may or may not have prescriptions for mental health drugs during the observed sample period (i.e., they may have a zero count, but with a nonzero probability of having a positive count). The zero-inflated process first models membership into the latent groups, then models the counts in the group with positive counts. Finally, the zero-inflated process determines observed probabilities as a combination of the probabilities for the two groups (Long and Freese 2006).

We developed multivariable models for any mental health drug utilization, as well as separate models estimating antidepressant and antipsychotic utilization. Analyses were not weighted due to the lack of longitudinal weights in the Cost and Use files. We use robust estimators to adjust the standard errors for clustering of observations due to the complex survey design. Wald's chi-square tests were used to test the hypotheses that gaps were significantly associated with odds of no prescriptions and counts of prescriptions (i.e., that all gap dummy variable coefficients were equal to zero). Statistically significant findings are assessed at $p < .05$ and $p < .10$ in our multivariable models. All analyses were performed using *Stata* version 9.

RESULTS

Description of Sample

Individuals with SMI meeting our study criteria accounted for 9.8 percent of Medicare beneficiaries. The characteristics of this sample are shown in Table 1. Forty-two percent were <65 years of age, representing a large representation of disabled beneficiaries. Severely mentally ill beneficiaries are predominantly female (58.6 percent), white (79.0 percent), and live in the South (40.5 percent). More than half reported good to excellent health (54.4 percent), 45.6 percent reported they had a mental health condition, and the mean count of comorbid conditions based on the DCG/HCC model was 10.1. On average, severely mentally ill survey respondents were in the 3-year sample frame for 33.6 months.

In our sample of severely mentally ill Medicare beneficiaries, 699 (77.6 percent) received at least one mental health medication during the study period. Beneficiaries receiving at least one such medication are significantly different than beneficiaries who do not on several counts, including age, health status, and time in the sample. Medication users were significantly more likely than nonusers to be younger than 65 years of age (48.3 versus 17.8 percent, respectively), more likely to self-report any mental health impairment (54.9

Table 1: Baseline Characteristics of Severely Mentally Ill Medicare Beneficiaries

	<i>Any Severe Mental Illness (n = 901)</i>	<i>% of SMI Mental Health Rx Users (n = 699)</i>	<i>% of SMI Non-Rx Users (n = 202)</i>
Total sample	100.0%	77.6%	23.4%
Age			
< 65	41.5	48.3*	17.8*
65–74	20.5	21.9*	15.8*
75+	38.0	29.8*	66.3*
Gender			
Female	58.6	57.8	61.4
Male	41.4	42.2	38.6
Race			
White	79.0	79.1	78.7
Nonwhite	21.0	20.9	21.3
Census region			
Northeast	22.1	21.9	22.8
Midwest	22.1	22.2	21.8
South	40.5	40.0	42.1
West	15.3	15.9	13.4
Self-reported health			
Poor to fair	45.5	49.6*	31.2*
Good to excellent	54.5	50.4*	68.8*
Self-reported mental illness	45.6	54.9*	13.4*
Mean HCC count	10.1	10.0	10.6
Mean months in sample	33.6	34.7*	29.6*

*Comparison of mental health drug users and nonuser statistically significant at $p < .05$.
SMI, severe mental illness; HCC, hierarchical coexisting condition.

versus 13.4 percent, respectively), and to be in the analytic sample for a longer period (34.7 versus 29.6 percent mean months, respectively). However, medication users were less likely to report good to excellent health (50.4 versus 68.8 percent, respectively).

Discontinuities in Prescription Drug Coverage, Income, and Drug Utilization

Among severely mentally ill Medicare beneficiaries, nearly half (48.2 percent) had continuous drug coverage over the entire time in the sample (Table 2). Nearly one in 10 (9.1 percent) experienced up to 25 percent of their time with coverage gaps, 10.3 percent experienced between 25 and 50 percent of their time in gaps, 11.9 percent experienced 51–99 percent of their time in drug coverage gaps, and the remaining 20.5 percent had no drug benefits whatsoever. For those with gaps, the mean number of gap months was 11.0

Table 2: Baseline Prescription Coverage Status and Use of Psychiatric Medications by Medicare Beneficiaries with Severe Mental Illness, 1997–2001

<i>Characteristics</i>	<i>Coverage Status % of Beneficiaries with Severe Mental Illness (n = 901)</i>	<i>Psychiatric Medication Use</i>	
		<i>% of SMI Rx Users (n = 699)</i>	<i>% of SMI Non-Rx Users (n = 202)</i>
Total sample	100.0%	77.6%	23.4%
Prescription coverage gaps in months*			
Full continuous coverage (0% gaps)	48.2	52.9	31.7
1–25% gaps	9.1	8.4	11.4
26–50% gaps	10.3	10.7	8.9
51–99% gaps	11.9	10.6	16.3
No coverage (100% gaps)	20.5	17.3	31.7
Mean gap months*	11.0	10.1	14.0
Federal poverty level (FPL)*			
FPL < 100%	21.1	20.2	24.3
FPL 101–150%	33.7	35.6	27.2
FPL 151–300%	21.1	22.0	17.8
FPL > 300%	24.1	22.2	30.7
Supplemental health insurance			
Medicare only	5.7	5.9	5.0
Medicaid	35.3	40.2*	18.3*
Other supplemental	42.1	41.1	45.5
“Mixed” supplemental	17.0	12.9*	31.2*
Psychiatric medication use			
Mean annual MH prescriptions	10.4	13.4	NA
Mean annual antidepressants	3.7	4.7	NA
Mean annual antipsychotics	2.5	3.2	NA

*Between group (SMI drug users versus SMI nondrug users) differences statistically significant at $p < .05$ or less.

SMI, severe mental illness; MH, mental health.

over 3 years. More users of mental health drugs had full prescription drug coverage than did nondrug users (52.9 versus 31.7 percent, respectively), but spent more time in gaps (36.1 versus 29.7 percent, respectively). The mean gap duration, however, was lower for medication users than nonusers (10.1 versus 14.0 percent, respectively).

More than one in five (21.1 percent) beneficiaries with SMI had a mean annual income at or below the FPL, and more than half (54.8 percent) would be eligible for income subsidization under the Part D benefit, assuming they met asset criteria. Differences in income by medication-use status were statistically

significant, with slightly more medication users (55.8 percent) putatively eligible for income subsidization compared with nonusers (51.5 percent).

The majority of beneficiaries meeting our criteria for SMI had at least one other form of supplemental health insurance, with only 5.7 percent possessing no supplemental coverage and the remainder enrolled in Medicaid (35.3 percent), another supplemental health insurance program (42.1 percent), or multiple types of coverage over the study period (17.0 percent). Medicare supplementation was found to significantly affect the probability of using any psychiatric medication. Persons with Medicare only comprised 5.9 percent of medication users but only 5.0 percent of nonusers. Those receiving Medicaid represented 40.2 percent of all medications users, but only 18.3 percent of nonusers. Beneficiaries with SMI and other sources of health insurance coverage, including multiple sources, represented a greater proportion of nonusers than users.

The mean annual number of mental health drugs received by the entire SMI sample was 10.4; among medication recipients, the mean was 13.4 psychiatric drugs. Beneficiaries with SMI used an average of 3.7 antidepressants (mean = 4.7 among antidepressant users) and 2.5 antipsychotics (mean = 3.2 among antipsychotic users).

Impact of Drug Discontinuities and Income on Receipt of Mental Health Drugs

After adjusting for covariates, gaps in drug coverage were statistically significantly associated with higher odds of receiving no mental health drugs (Table 3). Severely mentally ill Medicare beneficiaries with long-duration drug coverage discontinuities of 51–99 percent were significantly less likely than fully covered beneficiaries to receive any mental health drugs (OR = 1.96, $p < .05$), as were beneficiaries without any drug coverage (OR = 2.60, $p < .05$). Beneficiaries with gaps ranging from 1 to 25 percent of the study period also were somewhat more likely to not receive any psychiatric medications but the significance level was lower (OR = 1.84, $p = .091$).

Among individuals with SMI, drug coverage gaps >25 percent of the time were associated with lower medication usage levels (7.3 fewer medications for persons with gaps 51–99 percent of the time and 10.9 fewer medications for those without drug coverage). However, these results were not statistically significant.

Several covariates reached statistical significance. Beneficiaries aged 75 and older had 141 percent greater odds than younger beneficiaries of not receiving any mental health drugs. Among mental health drug users,

Table 3: Adjusted Odds Ratios for Not Receiving Any Psychiatric Medications and Percentage Change in Number of Psychiatric Medications Received by Users ($n = 901$)

	<i>Odds Ratios for Not Receiving at Least One Psychiatric Medication</i>	<i>% Change in Number of Psychiatric Medications</i>
Prescription coverage gaps in months		
Full continuous coverage (0% gaps)	1 (reference)	0 (reference)
1–25% gaps	1.84*	1.0
26–50% gaps	1.02	– 8.3
51–99% gaps	1.96**	– 7.3
No coverage (100% gaps)	2.60**	– 10.9
Federal poverty level (FPL)		
FPL $\leq$ 100%	0.99	– 17.9*
FPL 101–150%	0.85	– 8.8
FPL 151–300%	0.93	– 1.2
FPL $\geq$ 301%	1 (reference)	0 (reference)
Supplemental health coverage		
Medicare only	1 (reference)	0 (reference)
Medicaid	1.73	38.5
Other supplemental	1.27	– 1.9
“Mixed” supplemental	2.86*	13.3
Age		
< 65	1 (reference)	0 (reference)
65–74	0.86	– 31.4**
75+	2.41**	– 43.6**
Gender		
Male	1.36	– 17.0**
Female	1 (reference)	0 (reference)
Race		
White	0.90	18.2**
Nonwhite	1 (reference)	0 (reference)
Self-reported health		
Poor/fair health	0.53**	4.2
Good/excellent health	1 (reference)	0 (reference)
Self-reported mental illness	0.17**	89.9**
Mean HCC count	0.96*	0.1
Census region		
Northeast	1 (reference)	0 (reference)
Midwest	0.87	6.7
South	1.09	9.7
West	1.13	– 16.3
First year in MCBS survey		
1997	1 (reference)	0 (reference)
1998	0.90	3.1
1999	1.03	– 8.3

*Statistically significant at $p < .10$ or less.

**Statistically significant at $p < .05$ or less.

HCC, hierarchical coexisting condition; MCBS, Medicare Current Beneficiary Survey.

increasing age also reduced the number of mental health drugs received, with individuals aged 65–74 receiving 31.4 percent fewer drugs and those aged 75 and older receiving 43.6 percent fewer drugs than beneficiaries younger than 65. Beneficiaries in poor/fair health had 47 percent lower odds than healthier individuals of receiving at least one mental health drug, and higher (albeit not statistically significant) utilization rates. Beneficiaries who self-reported having a mental health condition in the past year had 83 percent lower odds of not receiving any mental health drugs than individuals who did not perceive themselves as mentally ill. Self-identified mentally ill beneficiaries received 89.9 percent more medications than those who do not self-identify as mentally ill. Although gender did not influence the probability of receiving psychoactive medications, it did influence the number of medications received, with males receiving 17.0 percent fewer mental health drugs than their female counterparts.

In large part, income and supplemental insurance failed to explain different medication utilization patterns in either segment of the model. However, two findings were marginally significant at $p < .10$ —beneficiaries possessing mixed supplemental insurance had 186 percent greater odds of not receiving any psychiatric medication relative to Medicare-only beneficiaries, and individuals falling in the lowest FPL bracket received 17.9 percent fewer psychiatric drugs than individuals in the highest FPL bracket.

Impact of Drug Discontinuities and Use of Antidepressants and Antipsychotics

Table 4 summarizes our findings relating to the impact of prescription coverage gaps on the utilization of antidepressant and antipsychotic drug medications (full models available upon request). Having no drug coverage (i.e., zero gaps) was the only measure significantly associated with higher odds of receiving no antidepressants. However, among beneficiaries receiving any antidepressant medications, those with drug coverage discontinuities of 26–50 or 51–99 percent were significantly more likely to receive fewer antidepressants than those fully covered (-23.8 and -25.8 percent, respectively) at $p < .05$. The odds of not receiving at least one antipsychotic were marginally significant ($p < .10$) for individuals experiencing drug discontinuities of 51–99 percent of their time in the sample. Among beneficiaries using at least one antipsychotic, only individuals in drug coverage gaps of up to 25 percent experienced significant reductions in antipsychotic use (33.2 percent fewer fills compared with fully covered antipsychotic using beneficiaries).

Table 4: Adjusted Odds Ratios for Not Receiving Any Antidepressants or Antipsychotics and Percentage Change in Number of Antidepressants and Antipsychotics Received by Users ($n = 901$)[†]

	<i>Odds Ratio for Not Receiving at Least One Psychiatric Medications</i>	<i>% Change in Number of Psychiatric Medications</i>
<i>Antidepressants</i>		
Prescription coverage gaps in months		
Full continuous coverage (0% gaps)	1 (reference)	0 (reference)
1–25% gaps	1.21	– 11.9
26–50% gaps	0.79	– 23.8**
51–99% gaps	0.95	– 25.8**
No coverage (100% gaps)	1.72**	– 12.7
<i>Antipsychotics</i>		
Prescription coverage gaps in months		
Full continuous coverage (0% gaps)	1 (reference)	0 (reference)
1–25% gaps	1.12	– 33.2*
26–50% gaps	1.03	– 0.4
51–99% gaps	1.84*	9.9
No coverage (100% gaps)	1.45	– 30.7

*Statistically significant at $p < .10$ or less.

**Statistically significant at $p < .05$ or less

[†]Controlling for age, federal poverty level, supplemental health insurance, gender, age, race, health status measures, census region, and cohort year.

DISCUSSION

This study is the first to document that discontinuities in prescription drug benefits impact both access to and the amount of mental health medication use in severely mentally ill Medicare beneficiaries. Relative to severely mentally ill beneficiaries with continuous prescription coverage, individuals with discontinuities in coverage were nearly two times more likely not to receive any medications to treat their mental illness. Similarly, beneficiaries without any prescription drug coverage are up to 2.6 times more likely not to receive any mental health medications. Although there is an inverse relationship between increased duration of prescription drug discontinuities and the number of mental health medications received, these relationships failed to reach statistical significance. The failure to find significant effects in both parts of the model may be a result of small sample size.

When we examined the two most frequently used mental health drug classes—antidepressants and antipsychotics—coverage gaps were differen-

tially associated with both higher odds of receiving no drug and reductions in the number of drugs received. Beneficiaries without any prescription drug coverage were most likely to experience impediments to antidepressant therapy. Among antidepressant users, beneficiaries with gaps in drug coverage received up to 25.8 percent fewer antidepressants relative to their fully covered counterparts. To a lesser degree, gaps in drug coverage also reduce the odds and number of antipsychotic utilization (at the 51–99 percent gap measure for odds of use and at the 1–25 percent gap measure for counts).

There are clear differences between severely mentally ill Medicare beneficiaries who use psychiatric medications and those who do not. For one, the latter are older and healthier, suggesting that younger, disabled, and presumably sicker beneficiaries have better access, through whatever means, to medications used to treat mental health problems. This is borne out in Table 2, which shows that persons with continuous prescription drug coverage represent over half (52.9 percent) of those with mental health drug use, but less than a third (31.7 percent) of nonusers. Beneficiaries with the highest odds of receiving psychiatric medications have incomes between 100 and 150 percent of poverty and are Medicaid recipients.

Several other characteristics of the study sample that influence utilization patterns of mental health drugs bear further mention. Increasing age is associated with reduced odds of mental health medication use, as well as reductions in the number of mental health prescription fills. This may be clinically justified if one takes the perspective that psychoactive medication use should be limited in older adults (Briesacher et al. 2005). On the other hand, it may be a signal that aged beneficiaries do not receive adequate pharmacologic treatment for many mental health problems; if so, our study suggests older beneficiaries, rather than younger ones who are SSDI eligible, may be most susceptible to discontinuities in prescription drug coverage.

Our finding that beneficiaries diagnosed with SMI who also self-define themselves as mentally ill have a better likelihood of receiving pharmacologic treatments—and more of it—than do individuals meeting diagnostic SMI criteria who fail to report their mental health problems. Mental illness carries a stigma, and this stigma may be especially prevalent among older adults. Coupled with age, this finding may help explain observed differences between users and nonusers of mental health medications.

Given the implementation of the Part D drug benefit of the Medicare Modernization Act, findings from this study suggest that severely mentally ill

beneficiaries warrant especial attention regarding access to medications necessary for adequate mental health treatment. This is true for a number of reasons, the primary one being that the standard benefit design of Part D provides beneficiaries with the possibility of experiencing major discontinuities in prescription drug coverage if the spending exceeds the initial coverage cap (\$2,250 in 2006) and they fall in the “doughnut hole.”

Our study suggests that gaps in drug coverage reduce the likelihood of receiving any mental health drug and, for individuals requiring antidepressant or antipsychotic drugs, the number of medications received. Given the chronic nature of SMIs like schizophrenia, depression, bipolar disorder, and other severe mental disorders, any interruptions or reductions in pharmacologic therapy may be detrimental to the patient in terms of comorbidity, quality of life, and even mortality. CMS has put several safeguards into place to prevent adverse selection of costly beneficiaries, including mentally ill beneficiaries, as well as exempting some classes of medications (including antidepressants, antipsychotics, and anticonvulsants) from formulary consideration. However, beneficiaries in the doughnut hole are still responsible for paying the entire cost of their mental health drug regimens out of pocket unless their plans provide some gap coverage.

The statistical model used in this study—a zero-inflated negative binomial model—is a rigorous approach to examine issues of medication use in this vulnerable population. Diagnostic tests such as the Vuong Z statistic for nonnested models (Long and Freese 2006) and graphs of probability distributions demonstrated that this model fit the data better than linear, Poisson, and uninflated negative binomial models (results available from authors upon request) (Cheung 2002).

Although robust, there are several limitations to consider in interpreting our findings. For one, several variables, including our independent measure of interest (drug coverage gaps) are based on respondent self-report. It is possible that respondents with SMI are unaware of their health insurance coverage. As well, there may be selection bias by respondents as to whether and type of supplemental coverage they procure.

Furthermore, we are limited by lack of available weights to provide national estimates of mental health medication use among severely ill beneficiaries; thus, our findings are only generalizable to the sample we describe. Also, our definition of severe mentally illness, based on one used by the Substance Abuse and Mental Health Administration (Buck et al. 2004), may not conform to other studies using one inpatient and/or two outpatient mental disorder diagnoses (Ross-Degnan et al. 2004; Simoni-Wastila et al. 2004) or to

those using different ranges of less severe or unclear depression symptomatology (e.g., we omitted individuals with ICD-9-CM depression diagnosis 311.xx labeled depression not otherwise classified). Because we wanted a homogeneous sample representing truly severely mentally ill Medicare beneficiaries, our definition is admittedly more conservative. The adoption of this more stringent definition also reduced the overall sample available for analysis, which, as we noted above, may contribute to nonsignificant findings.

We also are unable to clinically assess the severity of mental illness or response to medication, adherence to medication, or other factors that may be associated with medication use. In particular, we cannot determine whether failure to use medications stems from access issues related to drug coverage gaps or lack of adherence to prescribed regimens for noncost-related reasons. Our findings are consistent with those of Soumerai et al (2006) showing that cost-related medication nonadherence among Medicare beneficiaries is high, ranging from 29 percent among disabled beneficiaries to 13 percent among aged beneficiaries across all medications (Soumerai et al. 2006). Nonadherence due to clinical or other reasons remains unknown. As well, we do not know whether nonmedication users are receiving other, nonprescription remedies, such as psychotherapy, or alternative therapies not associated with a prescription (St. Johns's Wort, 5-HT). Both nonadherence and use of non-pharmacologic and alternative treatment modalities may potentially serve as substitutes for prescription medications.

Future research should strive to address these limitations, as well as examine whether discontinuities in drug coverage influence adverse outcomes, including impaired quality of life, increased morbidity, and death. In particular, it remains unknown whether reductions in drug use resultant from changes in drug coverage result in the increased use of other, nondrug services, such as emergency department visits, hospital admissions, and use of inpatient psychiatric services.

In conclusion, this study demonstrates that severely mentally ill Medicare beneficiaries who lack drug coverage—either continuously or periodically—face increased odds of not receiving any mental health medication. Of those who do receive at least one prescription, beneficiaries with less than full, continuous drug benefits receive fewer prescription fills than their fully covered peers. Our study suggests that continuous monitoring and evaluation of this population as they progress through the maze of Part D plans is necessary in order to insure adequate access to mental health medications.

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Simoni-Wastila, L., Blanchette, C., Ren, X., and Stuart, B. 2005. "Gaps in Drug Benefits: Impact on Utilization and Spending for Drugs Used by Medicare Beneficiaries with Serious Mental Illness." Podium presentation at the annual meeting of AcademyHealth, June 28, 2005, Boston, MA.

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