

Medicare Part D: Rough start for 'dual-eligibles'

APA surveys seek to quantify 'insurmountable hurdles'

Olanzapine? Not in the formulary; try clozapine instead. A 6-mg dose of risperidone? Not in the formulary; see if 2 mg will work. Patients stabilized off-label? Start preparing to wage a lengthy appeal.

We've all heard continuity-of-care horror stories about psychiatric patients who were transitioned from Medicaid to Medicare Part D's prescription drug plans (PDPs). The American Psychiatric Association (APA) is compiling data from two surveys to put numbers behind those anecdotes, says Sam Muszynski, JD, director of APA's Office of Healthcare Systems and Financing.

"A lot of people are spending countless hours trying to help patients sort this out," Muszynski told CURRENT PSYCHIATRY. "We've got to make sure people get their medications."

Preliminary results of a nationwide APA survey of 5,000 psychiatrists are expected next month, he said. A parallel 10-state survey is quantifying how many psychiatric patients couldn't get medications after April 1—when emergency safeguards and extensions ended—and how many wound up in emergency rooms or institutions or had other adverse clinical outcomes as a result.

APA will use its survey results to advocate on behalf of psychiatric patients before the Centers for Medicare and Medicaid Services (CMS), which administers the new prescription program.



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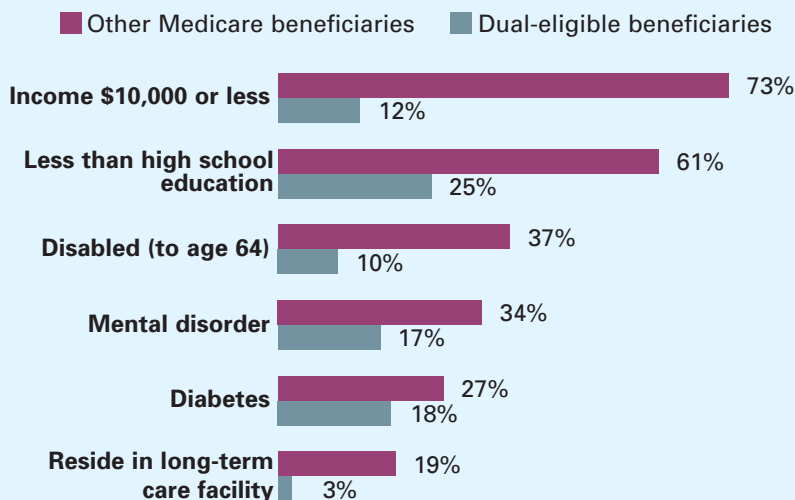
DUAL-ELIGIBLES' DILEMMA

More than 6 million low-income seniors and persons with disabilities qualify for both Medicaid and Medicare (*Figure, page 30*). These "dual eligibles," who had their drug coverage shifted from Medicaid to Medicare Jan. 1, accounted for nearly one-half of Medicaid drug spending, according to a report by the Kaiser Family Foundation (*see Related resources*). They were randomly enrolled into Medicare Part D's privately administered PDPs.

As you would expect, persons with psychiatric disorders—nearly one-third of the dual-eligibles, according to the Kaiser report—are hit the hardest, Muszynski said. "The problem with this system is

Figure

Profile of Medicare's dual-eligible beneficiaries



Number of dual-eligible beneficiaries: 7.0 million (2002)

Source: Centers for Medicare and Medicaid Services. Medicare Current Beneficiary Survey 2002, Access to Care File.

you are dealing with people who may be cognitively impaired, with impaired judgment or impaired planning abilities, and then you ask them to navigate an extremely complicated process.”

The APA warned the U.S. Senate Finance Committee in February that thousands of these patients could not get their medications because PDPs’ formulary rules are too complicated. Many patients have not gotten emergency 30-day transition supplies of medications because intended safeguards failed.

DRUG SAMPLES ‘FLYING OFF THE SHELVES’

Medicare Part D does not cover the cost of all medications but only those considered “medically necessary.” Antidepressants and antipsychotics are covered, for example, but the law that created Medicare Part D excluded benzodiazepines,

whether they are deemed medically necessary or not.

Meanwhile, drug samples have “been flying off the shelves,” Muszynski said, and crisis and advocacy groups have been inundated with pleas for help. “These patients have chronic, medically complex conditions, complicated by medical comorbidities,” he said. “You’re dealing with a heterogeneous, complex, vulnerable, medically ill population” (*see “Case: Denial of medications triggers panic attack”*).

Pharmacists and physicians are also flummoxed, Muszynski said, struggling with the nuances of dozens of plans. Most Medicare beneficiaries must choose

among 27 to 52 PDPs, whereas dual eligibles—because of subsidized co-pays—generally have only 6 to 16 plans to compare, depending upon where they live, the Kaiser report said.

COMMUNICATION BREAKDOWNS

Dual eligibles who did not enroll with a PDP before Jan. 1 were randomly assigned to PDPs without regard for their medications or diagnoses, according to Muszynski. The government did not want their coverage to lapse, he said, but “unfortunately this created seemingly insurmountable administrative and paperwork hurdles for everyone involved.”

Hundreds of physicians, pharmacists, and patients have contacted Muszynski’s office to report breakdowns in federal Medicare phone and computer communication systems, he said. “At this point, I can’t state in a statistically valid man-

ner how many were adversely affected, but we know the reports we've gotten represent only a tiny portion of them," Muszynski said. "It could be as high as 50% of all patients switched to Part D."

Muszynski's staff found it nearly impossible to get through to CMS' Medicare Part D assistance by calling 1-800-MEDICARE. Those who did get through to Medicare or to representatives at the individual plans often got incorrect or conflicting information and sometimes waited days for answers.

The CMS Web site (www.medicare.gov) also was difficult to use and seemed to crash when eligibility questions were too complicated. "Bottom line: people couldn't get their drugs," he said.

Barriers such as these discourage adherence, Muszynski said, and can start psychiatric patients on a downward spiral of crisis, emergency room admission, hospitalization, or even suicide. "A lot of these people are very fragile; if you disturb their habits you have an adherence issue," he said. "It no longer matters if they can get the drugs; they're now not going to take them."

PRESCRIBING CONSTRAINTS

Medicare Part D rules that make it difficult for psychiatrists to ensure that their dual-eligible patients get appropriate medications include:

- requiring prior authorization for "safety edits"

Box

Case: Denial of medications triggers panic attack

By Hani Raoul Khouzam, MD, MPH

Mr. A, age 68, is being treated for hypertension, panic disorder with agoraphobia, obsessive-compulsive disorder (OCD) and obsessive-compulsive personality disorder (OCPD). His panic and OCD have been stable for 3 years on clonazepam, 0.5 mg bid, plus sertraline, 100 mg at bedtime. He gets his medications from a pharmacy that was accepting Medicare recipients' prescriptions.

Because of his obsessive-compulsive traits, Mr. A rigidly observes appointments and deadlines. He followed all Medicare Plan D rules to the letter and enrolled on the first day it started in November 2005. In February 2006, he went to his pharmacy to refill his sertraline and clonazepam prescriptions.

That day, a substitute pharmacist who was not familiar with Medicare Plan D told Mr. A that "first of all," he needed to find a generic substitute for sertraline and "second of all," clonazepam was not covered under Plan D.

Mr. A was devastated. He knew that sertraline has no generic substitute and that his symptoms worsen without clonazepam. His anticipatory anxiety precipitated an instant panic attack, accompanied by fear of open spaces and recurrence of agoraphobic reactions. Fortunately, Mr. A's nephew—a family practice physician—provided a temporary supply of free sertraline and clonazepam samples.

Comment. Since Mr. A reported his ordeal, I have thought about complications that could have occurred if samples had not been available. These include:

- serotonin reuptake inhibitor interruption/discontinuation syndrome
- clonazepam withdrawal symptoms, including possible withdrawal seizures affecting his well-controlled hypertension
- frequent recurrence of panic with increased episodes of agoraphobia
- worsening of OCD and OCPD symptoms.

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- therapeutic substitution of drugs based on cost, not effectiveness
- step therapy (requiring initial failure on cheaper drugs before more-expensive drugs are allowed)
- dosage and quantity limits
- restrictions on off-label use
- co-payments, which many Medicaid plans did not charge
- unrealistic documentation requests to substantiate diagnosis and medication use.

Patients discharged after psychiatric hospitalization are at risk when their PDPs' formularies do not approve of drugs or dosages on which they were stabilized. Muszynski estimates that one-quarter to one-third of psychiatric patients are stabilized at higher-than-recommended dosages, and most PDPs consider this "off-label use" that they are not required to cover.

An example he has seen of step therapy is patients on olanzapine being forced to switch to clozapine. Then, if it fails, they can seek approval to go back on olanzapine. "Clinically, I can't think of a more absurd example," Muszynski said. "I'm not making this up."

'PHYSICALLY IMPOSSIBLE' APPEALS PROCESS

Despite promises by CMS officials, the exceptions and appeals process is not working, Muszynski said. In one case, the APA has assisted a psychiatrist whose patient was stabilized for more than 1 year at a higher-than-FDA-approved dosage of ziprasidone. The psychiatrist sought prior authorization to continue ziprasidone but was turned down by the PDP because of a "safety edit." Muszynski said safety edits "were supposedly designed to ensure that high dosages are intended but, in fact, are being used by PDPs to restrict access to medications or to force the physician to prescribe a lower dosage, regardless of a patient's history."

'Safety edits' are being used to force physicians to reduce dosages, regardless of a patient's history

The psychiatrist provided medical literature supporting her dosing decision, but the PDP denied the prescription again and on two subsequent appeals—a "coverage re-determination process" and an independent review. At presstime, her appeal awaited a hearing before an administrative judge, and appeals regulations do not say how quickly a hearing must be granted.

"You can't have a viable system to adjudicate exceptions if it's physically impossible to deal with; clinicians just don't have the time," Muszynski said.

The APA is directing patients and psychiatrists to its Web site (www.mentalhealthpartd.org) and working with other advocates to address individual and systemic problems. "There's a systemic problem, and CMS needs to do something systemic to correct it," Muszynski said. "The case-by-case approach is not working."

Related resources

- ▶ American Psychiatric Association Web site on Medicare Part D. www.mentalhealthpartd.org.
- ▶ Center for Medicare and Medicaid Services (CMS). www.medicare.gov; 1-800-MEDICARE.
- ▶ Kaiser Family Foundation. The Kaiser Commission on Medicaid and the Uninsured. Dual eligibles and Medicare Part D: an implementation update. www.kff.org/medicaid/7454.cfm.