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Levi Wells Prentice was born in 1851 in the small town of Harrisburg, New York. He grew up on a nearby farm in Lewis County, surrounded by the picturesque Adirondack Mountains. As a child, Prentice enjoyed oil painting, but he never had any formal art training. He did have a great deal of ambition, however. By the time Prentice was in his late teens, he had produced numerous landscape paintings of the Adirondacks.

In 1870, his father sold the farm and the Prentice family moved to Syracuse, New York. This new urban environment had a positive effect on Prentice’s artistic development; he made his public debut as a landscape painter at the age of 21. In an article found in the first edition of the Guide to the Adirondacks handbook, the editor extolled Prentice: “A visit to his studio in Syracuse, and an examination of his art collection, will prove a matter of rich enjoyment to any lover of the beautiful.”

Prentice was inspired by the work of the Hudson River School artists as well as the Old Masters. He was also influenced by photography, especially stereoscopic photography. (A stereoscope is a hand-held device that enables the viewer to see a 3-dimensional image by looking through magnifying lenses at a pair of 2-dimensional photographs.) According to Elizabeth Lindquist-Cock, author of The Influence of Photography on American Landscape Painting, 1839-1880, the use of rocks, fallen logs, and other debris in the immediate foreground is typical of the stereoscopic photograph. “[Stereography] used every means possible to make the spectator so conscious of 3-dimensional depth that he has the sensation of being inside the scene, not merely looking at it,” she notes. Prentice utilized similar techniques to achieve the illusion of 3 dimensions in his landscape paintings—he scattered carefully rendered objects in the dark foreground, painted a light, atmospheric background, and cropped the picture on all sides.

Prentice has been praised by art critics for his close study of nature. In Barbara L. Jones’ book Nature Staged: The Landscape and Still Life Paintings of Levi Wells Prentice, she observes: “Prentice’s fidelity to natural details reflected his keen interest in the natural sciences and the botanical and geological accuracy mandated by John Ruskin and the Pre-Raphaelites.” Prentice personalized his landscape images by combining minute details from his on-site sketches with exaggerated color and an idealized composition.

While living in Syracuse, the artist exhibited and sold his work in galleries, painted commissioned portraits, and taught painting classes. In addition to his accomplishments in fine art, he was a highly skilled craftsman, making all of his picture frames, easels, palettes, and brushes. Prentice also built houses and made furniture. He learned these trades from his brother, Albert, a carpenter, and his father, Samuel, a cabinetmaker.

In 1879, Prentice moved to Buffalo, New York, and 3 years later married an Englishwoman, Emma Roseloe Sparks. The couple moved to Brooklyn in the spring of 1883, just before the celebrated opening of the Brooklyn Bridge. They had 2 children, Leigh and Imogene.

Prentice began painting still lifes almost immediately after arriving in Brooklyn. His still life paintings are so realistic that some people actually try to brush away a lifelike fly found in a few of them. Prentice painted several types of still life arrangements: simple tabletop displays of fruits or vegetables, fruit casually composed in an outdoor setting, and living fruit still attached to a bough or bush. Apples were his favorite subject, but he also depicted a wide variety of fruits, including strawberries, peaches, plums, raspberries, cherries, pears, pineapples, grapes, and bananas. In Apples Spilling from a Basket, Prentice has painted such a convincing portrait of the fruit that a given viewer might be tempted to reach for one of the crisp, delicious apples. He cropped the composition to suggest that the image continues on both sides, and created a dramatic contrast by painting dark hues behind the brightly colored apples. Prentice added the finishing touch with his subtle rendering of the apples’ reflections on the highly polished tabletop.

In 1905, Prentice and his family moved to the Philadelphia area. He developed cataracts during his later years, which affected his ability to paint. Prentice died in Germantown, Pennsylvania, in 1935.

Noted art historian William H. Gerdts once remarked, “There are several paintings by Prentice in which he achieves a quality of illusionism which is unsurpassed.” In 1993, the Adirondack Museum in Blue Mountain Lake, New York, honored this “master of illusion” with a retrospective exhibition. Prentice’s many museum representations include the Detroit Institute of Arts; the Carnegie Museums of Pittsburgh; the Museum of Fine Arts, Boston; and the Hudson River Museum, Yonkers, New York.

Sheila Macho
Cover Editor

COVER CREDIT
Levi Wells Prentice, Apples Spilling from a Basket, oil on canvas. Brooklyn, New York, 1892. Copyright © Christie’s Images/CORBIS.

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About our cover artist
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REFERENCE

Drug Company Advertising in Medical Journals About the Health-Economic Advantages of Their Products for 2000-2006 Versus 1990-1999

Jennifer A. Palmer, MS; Alison R. Timm, BS; and Peter J. Neumann, ScD

ABSTRACT

BACKGROUND: Section 114 of the 1997 Food and Drug Administration Modernization Act (FDAMA) effective February 19, 1998, permitted some additional flexibility for drug companies to provide “health care economic information” to “a formulary committee or other similar entity” and may have caused a decline in economic messages used in print advertisements in medical journals. We previously investigated the promotional claims made by pharmaceutical companies about the economic advantages of their prescription products in print advertisements in 6 leading medical journals from 1990-1999.

OBJECTIVE: To examine the hypotheses that (1) economic promotion in journals declined after the effective date of Section 114 of the FDAMA, and (2) increased calls for U.S. Food and Drug Administration (FDA) scrutiny of health-economic information was associated with an increase in the reporting of supporting information for economic advertisements in 2000-2006 compared with the 1990s.

METHODS: Two researchers independently reviewed all pharmaceutical print advertisements in 3 issues each year of 3 general medical and 3 specialty journals (totaling 18 issues each year) from 2000 through 2006. The type of economic claim (e.g., advertisements using the words “price,” “costs less,” “value”) as well as the presence of supporting information for an advertisement’s claims (e.g., published studies) were tabulated using a standardized data collection form. The research method was similar to that used in previous research of economic claims in advertisements in the same 6 medical journals from 1990-1999, and we compared the results from previous research for 1990-1999 with the new findings for 2000-2006.

RESULTS: Our results are derived from 2,144 pharmaceutical advertisements in 3 issues each year of 3 general medical and 3 specialty journals (totaling 18 issues each year) from 2000 through 2006. Economic content occurred in 11.1% (237/2,144) of advertisements in the 1990s, and 7.6% (104/1,372) from 1990-1999 (P<0.001). The frequency of economic advertisements rose in the 1990s, to a peak in 1997 at 16.2% (31/191) (test for trend: P<0.001) and declined thereafter, reaching a low of 3.9% (9/234) in 2002 (test for trend: P<0.001) before rising again to 13.7% (25/182) in 2006 (test for trend: P=0.030). Economic claims centered mainly on direct costs (i.e., “less expensive”) and benefit design (i.e., “one co-pay”) and less on cost-effectiveness (i.e., “value”). The percentage of economic advertisements that included any supporting information was similar in the 1990s and 2000s (63.7% [151/237] vs. 61.5% [64/104], P=0.70). The source of information to support an advertisement’s economic claims shifted away from price information (e.g., “average wholesale price” or “Red Book”) towards published studies and “data on file.”

CONCLUSION: Drug companies continue to advertise the economic advantages of their products in medical journals, though the practice declined somewhat after the 1997 FDAMA Section 114 legislation. Use of supporting references in the body of advertisements has not improved over time. The promotion of health-economic information warrants more scrutiny by regulators and medical journal editors.

What is already known about this subject

- Previous research by the authors of the present study found economic messages in 237 (11.1%) of the 2,144 advertisements in 6 medical journals over the period from 1990 through 1999. The proportion of ads with economic content increased over time, from 8.9% in 1990 to 9.7% in 1999 (P=0.003). Most frequently, economic ads contained statements that drugs were “less expensive” or “cost less” than alternative treatments (50.6% of economic ads). Support for economic advertisements was clearly reported in 63.7% of cases and typically referred to published drug prices.
- A 2003 study of 287 different pharmaceutical advertisements in 6 Spanish medical journals revealed that 82.4% (84) of 102 retrievable references were randomized controlled trials (RCTs) and 44.1% (45) of the 102 were not substantiated by the cited reference. Only 0.8% (1/123) of promotional claims that were made referred to “cost.”
- Research published in 2006 for 84 unique pharmaceutical advertisements published in 4 specialty journals in rheumatology found that only 29.0% (87) of 300 references were RCTs, 49.4% (43) of which were determined to be “supporting” of the claim.
- Cooper and Schriger (2005) found that 28.8% of medical claims in 438 pharmaceutical advertisements in 10 U.S. medical journals in 1999 did not have references to support the claims, and 18.7% (135/721) of the references that were used cited “data on file.” Only 20.5% (18/88) of requests for “data on file” were found to be actually available.
What this study adds

- This is the most comprehensive study of economic messages in medical journal drug advertising and compares the findings of our previous research for the 1990s with 2000-2006.
- Economic content occurred in 11.1% (237) of 2,144 ads in 10 years in the 1990s, and 7.6% (104) of 1,372 ads in the 7 years from 2000 through 2006 ($P < 0.001$). Economic claims centered mainly on direct costs (i.e., “less expensive”) and benefit design (i.e., “one co-pay”) and less on cost-effectiveness (i.e., “value”).
- The present research suggests a potential influence of the FDAMA Section 114 of 1997 in a reduction of economic claims in drug advertisements with a subsequent increase beginning in 2002. The frequency of economic ads rose in the 1990s to a peak in 1997 at 16.2% (31/191) (test for trend: $P < 0.001$) and declined thereafter, reaching a low of 3.9% (9/234) in 2002 (test for trend: $P < 0.001$) before rising again to 13.7% (25/182) in 2006 ($P = 0.030$), a proportion higher than in 8 of the 10 years of the 1990s.
- The percentage of economic advertisements that included any supporting information was similar in the 1990s and 2000s (63.7% vs. 61.5%, $P = 0.70$). The source of information to support an advertisement’s economic claims shifted away from price information (i.e., “average wholesale price” [AWP] or “Red Book”) towards published studies and “data-on-file.”

Pharmaceutical advertisements in medical journals are pervasive. They represent 95% of journal display advertisements, and their page length can exceed that of a journal’s longest article. Many studies have examined clinical claims in journal drug advertising. In contrast, the economic content of journal drug advertisements has received limited notice.

The prevalence and transparency of claims about a drug’s economic advantage merits attention. First, promotional efforts by manufacturers influence physicians’ prescribing decisions, which have potentially important implications for patients’ health and financial burden. Second, many physicians believe that cost considerations will factor into their drug selections increasingly over the next several years, which suggests a growing niche for economic advertising to physicians. Rising prescription drug prices and patient out-of-pocket payments in the future may further increase the influence of economic advertisements on physician decision-making.

Finally, studies have indicated that many claims in medical journals about drugs are poorly substantiated. For clinical claims, advertisements are often deficient in the use of supporting information, the representativeness of the information, the quality of the information, the sponsorship of the information, and the availability of the information. For example, Cooper and Schriger (2005) found that 28.8% of medical claims in 438 pharmaceutical advertisements in 10 U.S. medical journals in 1999 did not have references to support the claims, and 18.7% (135/721) of the references that were used cited “data on file;” only 20.5% (18/88) of requests for “data on file” was found to be actually available. van Winkelen et al. (2006) found that only 49.4% (43) of 87 randomized controlled trials were determined to be “supporting” of the claim in 84 unique advertisements published in 4 specialty journals in rheumatology during 2002-2004. Poor substantiation might extend to claims about economic benefits as well.

Our goal in this study was to characterize prescription drug advertisements with economic claims in leading medical journals from 2000-2006 and to document the presence and type of supporting information for such advertisements. This paper builds upon our previous work on economic messages in pharmaceutical advertisements in medical journals from 1990-1999.

Our hypotheses stem from trends found in earlier work and reflect the policy context within which journal advertising lies. Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 changed the evidentiary requirements for submissions to drug formulary committees in managed care organizations (MCOs) from “substantial evidence typically demonstrated by two adequate and well-controlled trials” to “competent and reliable scientific evidence.” The new standard gives pharmaceutical manufacturers guidance and some additional flexibility in promoting economic messages to managed care audiences. Conceivably, manufacturers redirected their promotional efforts from medical journals to direct MCO communications – a medium with a potentially larger sales impact – in response to this change in evidentiary standards. Manufacturers may also have decreased use of economic claims but improved substantiation of those still used in response to concerns about economic promotion and calls for more FDA vigilance. We therefore hypothesized that the quantity of economic claims in medical journal advertising decreased after Section 114 went into effect and that, over time, the use of information to support economic claims made in journal pharmaceutical advertisements increased.

Materials and Methods

We examined all prescription drug print advertisements in 3 leading general medical journals (Annals of Internal Medicine, Journal of the American Medical Association, New England Journal of Medicine) and 3 leading specialty journals (Circulation, Gastroenterology, Neurology) for 3 issues per year (January, July, October, chosen arbitrarily), totaling 18 issues per year from 2000-2006. The methods are similar to those in our previous study of 1990-1999. We considered each advertisement as a single record, even if the same one appeared multiple times.
in our sample, to identify the frequency with which journal readers encounter promotional messages.

Our data collection form was based on our previous work and updated for clarity and completeness. Both forms (previous and current) included items on the type of economic claims contained anywhere in the body of the advertisement. We defined economic content as mentioning terms such as “price,” “less expensive,” “costs less,” “value,” “cost-effectiveness,” and “productivity.” In the updated form, we specified some new terms, such as “less hospitalization/less treatment,” “co-pay/cost-sharing,” “in community longer,” (as stated within the context of claiming delayed nursing home placement) and “formulary/coverage.” These terms were added because they represent potentially important, more specific economic claims with regards to insurance benefit design and “indirect” economic impact.

We documented use of supporting information for economic advertisements and types of supporting information used (i.e., “price information,” “data on file,” or “published studies”). “Price information” refers to several different resources on drug prices. One of these, the AWP or “average wholesale price,” is the “list price” reported to commercial publishers by drug companies that is used to inform levels of drug reimbursement. These publishers, also used in advertisements’ references, include the “Red Book: Pharmacy’s Fundamental Reference,” “First Databank, Inc.,” and “Scott Levin Formulary Drug Audit.” Other references that fall into this “price information” category include citations of “wholesale acquisition cost” (the amount a company charges a wholesaler for a pharmaceutical) and “weighted average cost” (the summed total of an average price per package of a drug during a certain time period multiplied by the number sold, and divided by the number sold).

Further, types of supporting information were classified as “data on file” if those words were used verbatim, or if other unpublished company documentation was cited, i.e. “formulary status report” or “formulary access status.” “Published studies” as a source consisted of published peer-reviewed studies, mostly, as well as a presentation at a professional membership conference, a published abstract, and an on-line patient registry.

We considered published sources to reflect more transparent and potentially better substantiating information than price information, in that price alone does not capture the full economic consequences of using a drug, whereas published studies may. We considered data on file to be the least transparent source of evidence. We recognize that published sources may not always reflect rigorous or appropriate evidence, but use this categorization for convenience and discuss this further in our limitations section.

Two trained readers extracted data from each advertisement. After completing the form individually, these 2 reviewers convened to decide upon the final consensus answers which were used for analysis. The Cochran-Armitage test for trend was used to assess the statistical significance of changes over time in the proportion of advertisements containing economic content by year. The Pearson chi-square test was used to assess the statistical significance of differences by time period in type of information used to support economic claims. The SAS 9.1 statistical software package was used to run all of our descriptive and inferential statistics.
We reviewed 1,372 drug advertisements for the 7-year period from 2000 through 2006 (compared with 2,144 advertisements from 10 years in the 1990s), representing 220 different drugs. The 1,372 total for 2000-2006 included 567 (41.3%) advertisements from general medical journals and 805 (58.7%) from specialty journals. Of this total, 788 (57.4%) were unique (each advertisement appeared an average of 1.8 times in our sample; SD = 1.2; range = 1-8).

Economic content appeared in 7.6% (104/1,372) of advertisements from 2000-2006, compared with 11.1% (237/2,144) from 1990-1999 (P < 0.001). While the economic advertisements appeared with similar frequency in the specialty journals across time periods (1990s: 8.6% [81/942] vs. 2000-2006: 8.5% [68/805]; P = 0.91), they declined in frequency in the general medical journals (1990s: 13.0% [156/1,202] vs. 2000-2006: 6.4% [n = 36/567]; P < 0.001). The frequency of economic advertisements rose in the 1990s to a peak in 1997 of 16.2% (31/191) (test for trend: P < 0.001) and declined thereafter, reaching a low of 3.9% (9/234) in 2002 (test for trend: P < 0.001) before rising again, to 13.7% (25/182) in 2006 (P = 0.030). (Figure 1)

In the 2000s, drug advertisements with economic promotion referred mostly to direct costs and/or benefit design (i.e., “co-pay,” formulary availability). (Table 1) This included mention of “less hospitalization/less treatment” (26.0% of economic advertisements), “formulary/coverage” (23.1%), “co-pay/cost-sharing” (19.2%), “price” (16.3%), and “cost less/less expensive” (14.4%). While 1990s advertisements cited terms that indicated the concept of cost-effectiveness (i.e., “economical,” “value,” “savings,” “cost-effective”), the 2000-2006 advertisements did at a significantly lower rate or not at all. (Table 1)

The frequency of supporting information for advertisements with economic claims has not changed over time (1990s: 63.7% [151/237] and 2000-2006: 61.5% [64/104]), although the type of citation used to support advertisements has varied (P < 0.001). In the 2000s, supporting information pertained less to price information (1990s: 90.1% [136/151] vs. 2000-2006: 43.7% [28/64]) and more to data on file (1990s: 9.3% [14/151] vs. 2000-2006: 40.6% [26/64]) and published studies (1990s: 6.6% [10/151] vs. 2000-2006: 35.9% [23/64]). (Figure 2)

Discussion
Our study sheds light on the evolving practice of economic promotion in medical journal advertisements. First, economic promotion in pharmaceutical advertising continues, increasing in recent years after a decline during 1998-2002. Second, the economic advertisements from 2000-2006 refer more to direct cost (i.e., “costs less,” “price,” affordable/affordability) than to indirect costs (“back-to-work”) and cost-effectiveness (“value”). Perhaps pharmaceutical companies favor such claims as more concrete and easier to substantiate.

Third, the overall use of substantiating information has not increased with time. Even when references are provided, questions about their transparency persist. On the positive side, more published studies have been referenced in recent years. On the other hand, references to “data on file,” a company’s in-house form of evidence which has not been published or peer-reviewed, also increased over time.

Our findings suggest the possible influence of external policies on promotional activities for drugs. In particular, the FDAMA Section 114 legislation in 1997 may have contributed to the decrease in economic advertisements in general medical journals post-1997. Section 114 may have precipitated a shift in drug company’s targeted audience from individual physicians making prescribing decisions at the patient level to formulary committees making coverage decisions at the health plan level.4 It is also possible that the increased scrutiny of economic promotion accompanying the legislation created a spillover chilling effect on its use in print advertising.22 The more recent increase in economic advertisements (post-2002) may reflect a renewed interest among drug companies in this type of promotion perhaps due to tougher competition in the generic market, heightened interest in cost by payers, typified by the release of versions of the Academy of Managed Care Pharmacy (AMCP) Format for Formulary Decisions (in 2000, 2002, 2005),23 which call for a
health plans to request economic data and models from drug companies, or increased comfort with the FDA’s relative lack of scrutiny over economic messages in ads.

Given the recent resurgence of economic advertisements after a decline in the late 1990s, the question of whether this trend is desirable or not warrants discussion. Economic claims in drug advertising offer potential benefits. Physicians believe that cost to the patient is an important consideration in their prescribing practice, though very few of them know the relative or absolute prices of the drugs they prescribe. With an advertisement possibly serving as an important introduction to a technology, physicians may be able to make better decisions on the value of drugs and guide their patients in doing the same. This could result in better clinical decisions and even significant cost savings for both the patient and the health care system. Providers could avoid more costly but equally effective products with accurate information or select products that cost more but offer good value.

The uncertain nature of much of the substantiating information that comes with less transparent practices, however, tempers these advantages. Indeed, as discussed before, the field is scattered with examples of biased, unsubstantiated, unavailable, and misleading clinical claims. For example, expert reviewers considered 34% of medical journal advertisements with clinical claims in need of major revisions, 28% not acceptable for publication, and, most importantly, 44% capable of causing inappropriate prescribing if journal advertisements served as the sole source of information.

Similarly with regard to economic claims, physicians could prescribe drugs on erroneous economic pretense if relying on misinformation. A prescription based on an unsubstantiated advertisement could result in foregone clinical, economic, and quality-of-life benefits. As with clinical claims, inaccurate or misleading economic claims could result in inadequate care from physicians. This effect may be unduly heightened given the credibility attributed to referenced claims that appear in medical journal advertising.

Accordingly, economic content in prescription drug advertisements may warrant more attention from journal editors and perhaps regulators. The FDA could help matters by establishing clear guidelines about what economic claims and what level of transparency are acceptable in promotions targeting providers and implementing an effective surveillance system to monitor compliance. This is particularly vital, as physician-targeted advertising generates the most FDA citations of any type.

Future research could help shed more light on this topic. Only 2 prior studies have assessed economic claims in drug advertising in medical journals. The first is outdated (published 1993), and, while finding prices advertised in nations with a public insurance model (out of 18 nations total), does not examine practices in the United States. The second, which targets Spanish medical journals, found “cost” claims only in 0.8% (1/125) promotional claims backed by supporting information. New studies should address this gap in the knowledge base about economic promotion of drugs in U.S. medical journals. Studies should also assess how and to what extent journal advertisements with economic messages influence physicians’ drug choices and whether or not that is a beneficial end-result. Other possible explanations of
the dip and subsequent rise in economic advertisements in the past decade, besides FDAMA Section 114’s influence, should be examined, such as an initial lack of familiarity followed by an increasing comfort level with FDA rules among pharmaceutical manufacturers.

To improve the transparency of journal drug advertisements, researchers could build upon this work by examining the representativeness, sponsorship, and availability of supporting information for economic promotion. Manufacturers, too, can help by supporting economic claims with rigorous and transparent scientific support that is readily available. Finally, journal editors might subject economic advertisements to more stringent peer and editorial review processes.7,29

**Limitations**

Our study has several limitations. One is the somewhat simplistic classification that we used to describe the sources of supporting information. We did not examine the quality or level of evidence in sources such as “data on file” or published studies. Instead, we defined published studies as more transparent than price information (i.e., “average wholesale price” or “Red Book”) and, in turn, price information as more transparent than data on file, a relatively crude metric. Second, the number of economic claims in the 2000s may be inflated due to the inclusion of new economic terms in the data collection instrument for 2000-2006. This effect may have contributed to the increase in economic advertisements in the mid-2000s. Third, we did not determine inter-rater reliability but instead used a consensus measure. This method does not permit examination of the role of bias in our results.

Fourth, our reviewers in this study were different individuals than those who reviewed the 1990-1999 data and may have categorized the information differently. Fifth, the advertisement content in the leading medical journals in our sample may not be representative of the advertisement content in all medical journals. Finally, our study does not include other important areas of pharmaceutical promotion such as direct-to-consumer advertising, physician detailing and sampling, which are fertile ground for investigation of economic promotional practices.

**DISCLOSURES**

This research was funded by Novartis Pharmaceuticals in the form of an unrestricted grant. Neumann has received grant funding from various nonprofit foundations such as the Robert Wood Johnson Foundation and government agencies and has served on advisory boards for Merck, Schering Plough, and Johnson & Johnson and is a recipient of grant funding from Elan Pharmaceuticals.

Peter Neumann was responsible for study concept and design. Jennifer Palmer and Alison Timm collected the data. Timm conducted the data analyses, and all 3 authors shared in data interpretation. Palmer performed the majority of the writing of the manuscript with assistance from Neumann. Palmer, Timm, and Neumann revised the manuscript after peer review.

**REFERENCES**


Drug Company Advertising in Medical Journals About the Health-Economic Advantages of Their Products for 2000-2006 Versus 1990-1999

APPENDIX A

SEC. 114. Health Care Economic Information

(a) In General.--Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: “Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term ‘health care economic information’ means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.”

<<NOTE: 21 USC 352 note.>>

(b) Study and Report.--The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

Association Between Cardiometabolic Risk Factors and Body Mass Index Based on Diagnosis and Treatment Codes in an Electronic Medical Record Database

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ABSTRACT

BACKGROUND: Managed care organizations (MCOs) have access to treatment and diagnosis information from administrative claims data but generally have limited or no access to clinical information about laboratory values or biometric values such as body mass index (BMI) or waist circumference. Thus, MCOs are generally unable to identify overweight patients with cardiometabolic risk factors that put them at a high risk of poor outcomes. The National Heart, Lung, and Blood Institute defines normal body weight as a BMI (ratio of weight in kilograms to height in meters squared [kg/m²]) from 18.5 to 24.9 kg/m², overweight as 25.0 to 29.9 kg/m², and obesity as a BMI of 30 kg/m² or greater. Current guidelines for weight-loss pharmacotherapy, including U.S. Food and Drug Administration-approved label indications, specify use in patients with a BMI of 30 kg/m² or greater, or a BMI >27 kg/m² and at least 1 concomitant cardiometabolic risk factor such as controlled hypertension, diabetes, or dyslipidemia.

OBJECTIVE: To evaluate the association of cardiometabolic risk factors with BMI as recorded in a database of electronic medical records (EMRs).

METHODS: Each patient had a minimum look-back observation period of 2 years from the last date of activity in the EMR. Patients with a BMI of 18 kg/m² or greater recorded in the EMR at any time during the 10-year period from January 1996 through December 2005 were stratified into groups by the number of cardiometabolic risk factors and by individual cardiometabolic risk for those with just 1 risk factor. Cardiometabolic risk factors were identified from diagnoses and prescription orders in the EMR associated with high triglyceride levels, low high-density lipoprotein cholesterol (HDL-C) levels, type 2 diabetes, or hypertension. Unadjusted and adjusted odds ratios (ORs) of having a BMI >27 kg/m² were calculated for each risk factor group and for patients with no risk factors. Logistic regression analysis, ORs were adjusted for age, gender, insurance type, region, medications associated with weight gain or weight loss, and diseases that modify weight.

RESULTS: A total of 499,593 patients with a BMI of 18 kg/m² or greater were identified; 56.4% (n = 281,988) had a BMI >27 kg/m², whereas 43.6% (n = 217,605) had a BMI between 18 and 27 kg/m². Compared with patients with no risk factors (n = 289,960), patients with 1-4 risk factors (n = 209,633) were significantly more likely to have a BMI >27 kg/m², 48.4% of patients without cardiometabolic risk factors had a BMI >27 kg/m²; compared with patients with no risk factors, the odds of having a BMI >27 kg/m² were multiplied by 1.45-5.07, depending on the type and number of risk factors. Diagnoses and treatment indicators for cardiometabolic risk factors are potential indicators of obesity.

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What is already known about this subject

- Managed care organizations (MCOs) generally have access to treatment and diagnosis information from administrative claims data but may have limited or no access to clinical information about laboratory values or biometric readings. In the absence of clinical data about body mass index (BMI) and waist circumference, MCOs may be unable to identify overweight patients with cardiometabolic risk factors that put them at an increased risk of poor outcomes.
- Patients with a BMI >27 kg/m² (ratio of weight in kilograms to height in meters squared) and at least 1 cardiometabolic risk factor are potential candidates for weight-loss pharmacotherapy according to U.S. Food and Drug Administration-approved labeling.
- Stafford and Radley found that 71% of patients who received weight-loss pharmacotherapy had no reported medical conditions other than obesity.
- Although the association between BMI and cardiometabolic risk factors has been extensively studied, there is no published research on prediction of BMI from administrative claims data.

What this study adds

- The presence of cardiometabolic risk factors multiplies the odds of having a BMI >27 kg/m² by 1.45-5.07, depending on the type and number of risk factors. The results demonstrate the association between cardiometabolic risk factors and the likelihood of being overweight using an electronic medical record that contains biometric and clinical laboratory data.
- Further development of this concept may allow health plans to identify patients who may be potential candidates for weight-loss pharmacotherapy based on whether they have been diagnosed or treated for cardiometabolic risk factors identifiable in administrative claims.
Cardiovascular disease is a leading cause of mortality in the United States and a significant driver of health care costs. Health care providers and payers recognize the value of aggressively identifying those at risk and treating the underlying risk factors for cardiovascular disease to help prevent poor outcomes. The identification of underlying cardiometabolic risk factors (lipids, blood pressure, and glucose indicators) is potentially important to slowing cardiovascular disease progression and minimizing the economic consequences for a health plan.

The third report of the National Cholesterol Education Program–Adult Treatment Panel (NCEP-ATP III) identified the cardiometabolic risk factors as central obesity, dyslipidemia (hypertriglyceridemia and low levels of high-density lipoprotein cholesterol [HDL-C]), impaired glucose tolerance, and elevated blood pressure. As a risk factor, obesity is independently associated with cardiometabolic risk, and obesity contributes to the development of the other risk factors. Thus, reduction in weight can both directly minimize obesity-related risk and indirectly reduce other cardiometabolic risks by improving low-density lipoprotein cholesterol and triglyceride profiles, reducing blood pressure, and improving insulin sensitivity.

In the United States, some payers provide coverage for weight-loss interventions, including bariatric surgery, individual dietary counseling, and to a lesser extent, weight-loss drugs; however, coverage varies. Although evidence has been published on the short-term clinical and economic benefits of weight loss in reducing risk for other cardiometabolic risks, without readily available evidence from their own health care systems, payers may be skeptical about coverage of weight-loss interventions. Additionally, appropriate targeting of these interventions may be difficult to achieve; Stafford and Radley found that 71% of U.S. patients who received weight-loss pharmacotherapy in 1996 had no reported medical conditions other than obesity.

Even when weight-loss interventions are covered, reimbursement for such interventions may require prior approval based on documentation of obesity, to avoid inappropriate use in individuals not at a body mass index (BMI) associated with medical risk. However, payer efforts to identify overweight and obese patients with cardiometabolic risk for weight-loss interventions are generally limited to analyses of administrative (reimbursement) claims data.

Claims data include diagnosis and treatment (procedure) codes, which are valuable in helping payers identify patients with commonly treated conditions such as hypertension, diabetes, and dyslipidemias, but are of limited value in identifying patients with obesity. Only 38% of obese patients receive a formal medical diagnosis for that condition. Claims do not capture biometric data such as weight and waist circumference or BMI, which would be the most effective means of identifying obese patients. Thus, in the absence of clinical data about BMI or weight and waist circumference, managed care organizations may be unable to identify overweight patients with cardiometabolic risk factors that put them at a high risk of poor outcomes.

The purpose of this study is to identify individuals diagnosed with cardiometabolic risk factors, including diabetes, hypertension, or dyslipidemia, based on indicators readily available in claims data (dispensed drugs and diagnoses) and evaluate whether these individuals are also overweight based on biometric data available in an electronic medical record (EMR) database, but not generally available to payers. This work examines the association in EMRs between risk factors, as indicated by diagnoses and prescription orders, and BMI to suggest the possible feasibility of permitting health plans to use information commonly available in administrative claims data to estimate the likelihood of obesity in their members.

Methods

Study Design

This study was an observational cross-sectional study of patients, about 64% of whom were treated in primary care physician (PCP) practice settings.

Source

The data source used for this project was the General Electric (GE) Centricity research database. Centricity (GE Healthcare, Waukesha, Wisconsin) is an EMR system that enables ambulatory care physicians and clinical staff to document patient encounters, streamline clinical workflow, and securely exchange clinical data with other providers, patients, and information systems. Centricity EMR is used by more than 20,000 clinicians to manage about 30 million patient records in 49 states, making it a widely used ambulatory care EMR. The data for this study were provided by a subset of approximately 9,000 Centricity practitioners from more than 100 practice sites located in 35 states that contributed medical record data for the patients they treat to the Medical Quality Improvement Consortium to create a research database. Approximately 64% of the submitting clinicians are PCPs, and the others are in various medical specialties. This EMR system replaces the paper medical record for the patients in the participating medical offices. The resulting research database provides information reflective of the clinical data captured in the practice setting, including diagnoses, chief complaints, medication orders, medication lists (patient-reported prescription and over-the-counter drug use), laboratory orders and results, and biometric readings. Data are collected centrally and go through a quality control process to clean the data and remove invalid values.

Study Population and Time Frame

The study population was drawn from the GE EMR population that had any activity from January 1996 through December 2005. Subjects were included in the analysis if they met the following criteria:
1. Aged 20 years or older on their last activity date to ensure that patients were at least 18 years of age during the entire 2-year observation period
2. Evidence of a clinical encounter within the previous 2 years, defined as a documentation of interaction between the physician office and patient for any reason. The observation period for each subject was the 2-year period before the patient’s last activity date.
3. At least 1 BMI measure recorded or calculated during the 2-year observation period that was at least 18 kg/m² (ratio of weight in kilograms to height in meters squared).

**Study Variables**

BMI values in the EMR database were recorded by clinicians or were calculated automatically from patient height and weight values. If there was more than 1 BMI value in the 2-year period for each patient, the BMI value closest to the midpoint (365 days) was used. NCEP-ATP III and International Diabetes Federation guidelines use waist circumference as a measure of central or abdominal obesity, but waist circumference is rarely available in clinical data. Therefore, BMI was used as a proxy measure and calculated from the patients’ height and weight measurements. Several studies have concluded that BMI and waist circumference are highly correlated to each other, and that each independently contributes a significant risk for metabolic syndrome and chronic diseases.

The National Heart, Lung, and Blood Institute defines overweight as a BMI of 25-29.9 kg/m² and obesity as a BMI >30 kg/m². Weight-loss drugs are approved by the U.S. Food and Drug Administration as adjuncts to diet and exercise in patients with a BMI of 30 kg/m² or greater, or a BMI >27 kg/m² for patients with 1 or more concomitant risk factors, including hypertension, dyslipidemia, and type 2 diabetes. An objective of this study is to provide data on the risk of patients being overweight when they have other cardiometabolic risk factors. Thus, in calculating the odds ratios (ORs) for the outcome measure, a BMI >27 kg/m² was used.

Independent variables used in this study were the presence of a diagnosis or prescription order indicative of any of 4 risk factors: high triglycerides, low level of high-density lipoprotein cholesterol (HDL-C), hypertension, and type 2 diabetes. Patient records were evaluated for the 2-year observation period to ascertain whether patients had 1 or more International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes documented as a problem anywhere in the EMR during the 2-year observation period or 1 or more prescription orders for any of the risk factors. Based only on the diagnosis and prescription data for the 2-year observation period, patients were categorized into groups: (a) no risk factors versus at least 1 risk factor, (b) 4 groups for each of the individual risk factors, and (c) 3 groups of multiple-risk factors (2, 3, or 4 risk factors) without regard to the specific risk-factor combinations.

Patients with individual risk factors were identified to assess the association of the individual risk factors with a BMI >27 kg/m². In addition, patients were categorized by age group: 18-30 years, 31-45 years, 46-64 years, 65-79 years, and 80 years or older, representing important age categories related to cardiometabolic risk and insurance coverage.

Additional demographic, clinical, and treatment covariates were captured, including gender, geographic location, and insurance status. Medications in the EMR database are identified by name and by Medi-Span Generic Product Identifier (GPI); covariates of cardiometabolic risk factors were identified by GPI drug category for medications that are (a) associated with weight gain or weight loss, (b) affect lipid profiles, or (c) associated with the development of cardiometabolic risk factors. These medications included antidepressants, oral antidiabetic agents and insulin, anticonvulsants, antipsychotics, antiretrovirals, progesterone, corticosteroids, and weight-loss agents. Diseases that were controlled for included hypothyroidism (identified using ICD-9-CM codes 243 for congenital hypothyroidism and 244.x for acquired hypothyroidism), type 1 diabetes (identified using ICD-9-CM codes 250.x1 and 250.x3) and polycystic ovaries (identified using ICD-9-CM code 256.4).

**Analysis**

Descriptive statistics for patients in each of the risk factor groups by BMI category were computed to show characteristics such as age, gender, geographic region of residence, and insurance status of each group. Between-group differences were analyzed using a Pearson chi-square test of significance.

Unadjusted and adjusted ORs for having a BMI >27 kg/m² were calculated for patient groups with individual cardiometabolic risk factors (reference categories: patients without the risk factors) and for groups defined by the count of risk factors (1, 2, 3, or 4, with 0 risk factors as the reference category). To calculate the adjusted ORs, logistic regression was used, adjusting for age group, gender, geographic region of residence (Southeast, Midwest, or West, with Northeast as the reference group), insurance type (Medicare, Medicaid, self-pay, or other/unknown, with commercial insurance as the reference group), and drug and disease covariates. Predictive probabilities of having a BMI >27 kg/m² were obtained from the adjusted logistic regression model and compared against the actual observations in the dataset for accuracy of predictions. The receiver operating characteristic (ROC) curve procedure in SPSS 16.0 (SPSS Inc., Chicago, IL) was used to calculate a c-statistic for the adjusted logistic regression model. The area under the ROC curve (c-statistic) is a measure of the discriminatory power of the logistic regression. The value of c-statistic ranges from 0 to 1, with 1 indicating the highest (perfect) predictive ability and 0.5 indicating a model with a predictive ability not better than random chance.

This study was deemed exempt by the University of Utah Institutional Review Board in a letter received September 1,
2006, based on a determination that the study was a retrospective analysis in a Health Insurance Portability and Accountability Act-compliant, deidentified database.

Results

The eligible population for this study included 3,216,323 patients aged 20 years or older on their last EMR activity date. Of the eligible population, 1,519,639 (47.3%) met the criteria of at least 1 interaction with a physician office within the previous 2 years. Of these patients, 505,693 (33.3%) had at least 1 BMI value; 499,393 patients (32.9%) who had at least 1 BMI measurement of 18 kg/m² or greater were included in the study. Figure 1 shows the selection of the final study population.

Table 1 describes the population demographics. Mean (SD) age of the population was 52.8 (17.5) years, and women comprised 61.9% of the population. The proportion of patients with a BMI >27 kg/m² increased with age up to 65 years (43.3%, 56.5%, and 64.4% for age groups 18-30 years, 31-45 years, and 46-64 years, respectively) and then began to fall (58.1% and 39.0% for patients aged 65-79 years and 80 years or older, respectively). A higher proportion of male patients (62.4%) had a BMI >27 kg/m² than did female patients (52.8%). Medicaid patients (62.1%) were more likely to have a BMI >27 kg/m² than were patients enrolled in other insurance types (commercial, 56.6%; Medicare, 54.8%; self-pay: 51.4%; and other/unknown, 57.6%). The proportion of patients with a BMI >27 kg/m² was higher in the Southeast (59.1%) and Midwest (58.3%) than in the Northeast (53.9%) and West (52.4%). P values for all comparisons were statistically significant at P<0.001 due to the large sample size.

Considering all cardiometabolic risk factors except the dependent variable of weight, 58.0% (289,960) of the study sample had no cardiometabolic risk factors and 42.0% (209,633) had 1 or more cardiometabolic risk factors. Overall, and for each individual risk factor, the proportion of patients identified by drug treatment alone (using the criteria shown in Appendix 1) was notably higher (66.9%) than the proportions identified by diagnosis (11.4%) or by both diagnosis and drug treatment (21.7%, Table 2). A similar trend was observed in patients with multiple cardiometabolic risk factors. The proportion of patients identified by treatment was significantly higher than the proportions identified by diagnosis or both diagnosis and treatment for each risk factor.

Of patients with 1 or more cardiometabolic risk factors, 157,586 (75.2%) had just 1 risk factor and 52,047 (24.8%) had multiple risk factors (Figure 1). Among patients with only 1 risk factor, the proportion of patients with hypertension was the highest (n=141,852; 90.0%), followed by patients with type 2 diabetes (n=10,866; 6.9%), elevated triglycerides (n=3,667; 2.3%), and low HDL-C (n=1,201; 0.8%). In the group of patients with multiple risk factors, a similar trend was observed; hypertension was the most common risk factor (n=50,742; 97.5%). The next most common risk factor was type 2 diabetes (n=42,876; 82.4%), followed by elevated triglyceride levels (n=12,162; 23.4%) and low HDL-C levels (n=4,866; 9.3%).

Among patients with 1 cardiometabolic risk factor, the proportion of patients with a BMI >27 kg/m² was higher in patients with diabetes (75.2%) than in patients with elevated triglyceride levels (70.6%), hypertension (62.2%), or decreased HDL-C levels (61.9%, P<0.001; Table 1). In patients with multiple risk factors (2, 3, and 4 risk factors) the percentage of patients with a BMI >27 kg/m² ranged from 79.8% to 88.5%.

When evaluating BMI by the presence of medication and disease covariates, the most notable finding was related to the concurrent presence of medications that influence body weight. The use of oral antidiabetic agents that cause weight gain or weight loss, and other weight-loss drugs was approximately 3 times higher for the group with a BMI >27 kg/m² (weight gain, 7.5%; weight loss, 7.7%) than for the group with a BMI of 27 kg/m² or lower (weight gain, 2.5%; weight loss, 2.0%).

Table 3 presents unadjusted ORs and adjusted ORs derived from logistic regression models, assessing the association between the 4 cardiometabolic risk factors and a BMI >27 kg/m². The model was adjusted for age, gender, geographic region of residence, insurance type, and concomitant medications likely to influence weight. Indicators for type 1 diabetes and polycystic ovaries were dropped from the regression model due to multicollinearity (i.e., high correlation with variables indicating use of antidiabetic agents).

When compared with the 18-30 age group, all age categories (31-45 years, 46-64 years, and 65-79 years) indicated a significant increase in the adjusted OR of having a BMI >27 kg/m² (ORs=1.50, 1.66, and 1.07, respectively; P<0.001), except for patients aged 80 years or older, who were less likely to have a BMI >27 kg/m² (OR=0.50, 95% confidence interval [CI] =0.49-0.52). Furthermore, male patients (OR=1.41, 95% CI =1.39-1.42) were significantly more likely than female patients to have a BMI >27 kg/m².

In the insurance type category, Medicaid patients were significantly more likely (OR=1.32, 95% CI =1.27-1.37), and self-pay patients were significantly less likely (OR=0.92, 95% CI =0.87-0.98) to have a BMI >27 kg/m² than were patients with commercial insurance. The adjusted results show that the odds of having a BMI >27 kg/m² was significantly higher for patients having any single cardiometabolic risk factor, including elevated triglyceride levels (OR=2.21, 95% CI =2.05-2.37), decreased HDL-C levels (OR=1.45, 95% CI =1.29-1.63), hypertension (OR=1.91, 95% CI =1.88-1.94), and type 2 diabetes (OR=2.64, 95% CI =2.51-2.77), compared with patients with no risk factors. The odds of having a BMI >27 kg/m² was significantly increased for patients who had any 2 of the risk factors (OR=3.58, 95% CI =3.47-3.69), any 3 of the risk factors (OR=4.24, 95% CI =3.93-4.59), and all 4 risk factors (OR=5.07, 95% CI =3.77-6.81). All of the above effects were in comparison with those patients who had none of the 4 cardiometabolic risk...
Association Between Cardiometabolic Risk Factors and Body Mass Index Based on Diagnosis and Treatment Codes in an Electronic Medical Record Database

FIGURE 1  Identification of Study Population From EMR Database

EMR patient population: ≥20 years old on last activity date 1996-2005 N=3,216,323

Patients with 2 years of continuous EMR activity n=1,519,639 47.2%

Eligible patients with BMI values n=505,693 33.3%

Patients with a BMI ≥18 kg/m² n=499,593 98.8%

Study population: BMI ≥18 kg/m² and no cardiometabolic risk factors n=289,960 58.0%

Study population: BMI ≥18 kg/m² and 1 or more cardiometabolic risk factors per ICD-9-CM or Rx orders n=209,633 42.0%

Patients with individual risk factors n=157,586 75.2%

Patients with multiple risk factors* n=52,047 24.8%

Elevated triglycerides n=3,667 2.3%

Low HDL-C n=1,201 0.8%

Elevated triglycerides n=12,162 23.4%

Low HDL-C n=4,866 9.4%

Hypertension n=141,852 90.0%

Type 2 diabetes n=10,866 6.9%

Hypertension n=50,742 97.9%

Type 2 diabetes n=42,876 82.4%

*Risk factors sum to >100% because patients with multiple risk factors were counted in all applicable risk factor categories.

BMI=body mass index; EMR=electronic medical record; GE=General Electric; HDL-C=high-density lipoprotein cholesterol; ICD-9-CM=International Classification of Diseases, Ninth Revision, Clinical Modification; kg/m²=ratio of weight in kilograms to height in meters squared; Rx=prescription.
### Table 1: Descriptive Characteristics of the Study Population, Cardiometabolic Risk Factors, and Medications by BMI in 499,593 Patients

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<thead>
<tr>
<th>Age (Years)</th>
<th>Total</th>
<th>BMI 18-27 kg/m²: n = 217,605 (43.56%)</th>
<th>BMI &gt;27 kg/m²: n = 281,988 (56.44%)</th>
<th>Pearson Chi-Square Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>n (row)</td>
<td>% in Group</td>
<td>% by BMI</td>
</tr>
<tr>
<td>Age (Years)</td>
<td></td>
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<tr>
<td>18-30</td>
<td>64,158</td>
<td>36,408</td>
<td>56.7</td>
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<tr>
<td>31-45</td>
<td>113,811</td>
<td>49,491</td>
<td>43.5</td>
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<td>46-64</td>
<td>174,214</td>
<td>62,069</td>
<td>35.6</td>
<td>20.4</td>
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<tr>
<td>65-79</td>
<td>106,209</td>
<td>44,495</td>
<td>41.9</td>
<td>11.6</td>
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<tr>
<td>≥80</td>
<td>41,201</td>
<td>25,142</td>
<td>61.0</td>
<td>11.6</td>
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<td>Gender</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Female</td>
<td>309,100</td>
<td>145,915</td>
<td>47.2</td>
<td>67.1</td>
</tr>
<tr>
<td>Male</td>
<td>190,493</td>
<td>71,690</td>
<td>37.6</td>
<td>32.9</td>
</tr>
<tr>
<td>Insurance Type</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Commercial</td>
<td>268,097</td>
<td>116,408</td>
<td>43.4</td>
<td>53.5</td>
</tr>
<tr>
<td>Medicare</td>
<td>117,231</td>
<td>52,958</td>
<td>45.2</td>
<td>24.3</td>
</tr>
<tr>
<td>Medicaid</td>
<td>11,171</td>
<td>4,234</td>
<td>37.9</td>
<td>1.9</td>
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<tr>
<td>Self-pay</td>
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<td>2,021</td>
<td>48.6</td>
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<tr>
<td>Other/unknown</td>
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<td>41,984</td>
<td>42.4</td>
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<td>Geographic Region</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>142,668</td>
<td>65,767</td>
<td>46.1</td>
<td>30.2</td>
</tr>
<tr>
<td>Southeast</td>
<td>122,808</td>
<td>50,206</td>
<td>40.9</td>
<td>23.1</td>
</tr>
<tr>
<td>Midwest</td>
<td>165,054</td>
<td>68,791</td>
<td>41.7</td>
<td>31.6</td>
</tr>
<tr>
<td>West</td>
<td>69,063</td>
<td>32,841</td>
<td>47.6</td>
<td>15.1</td>
</tr>
<tr>
<td>Risk Factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>289,960</td>
<td>149,555</td>
<td>51.6</td>
<td>68.7</td>
</tr>
<tr>
<td>Cardiometabolic Risk Factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 risk factor only</td>
<td>157,586</td>
<td>57,871</td>
<td>36.7</td>
<td>26.6</td>
</tr>
<tr>
<td>Elevated TG only</td>
<td>3,667</td>
<td>1,078</td>
<td>29.4</td>
<td>0.5</td>
</tr>
<tr>
<td>Low HDL-C only</td>
<td>1,201</td>
<td>458</td>
<td>38.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Type 2 diabetes only</td>
<td>10,866</td>
<td>2,690</td>
<td>24.8</td>
<td>1.2</td>
</tr>
<tr>
<td>Hypertension only</td>
<td>141,852</td>
<td>53,645</td>
<td>37.8</td>
<td>24.7</td>
</tr>
<tr>
<td>2 risk factors</td>
<td>45,938</td>
<td>9,257</td>
<td>20.2</td>
<td>4.3</td>
</tr>
<tr>
<td>3 risk factors</td>
<td>5,666</td>
<td>870</td>
<td>15.4</td>
<td>0.4</td>
</tr>
<tr>
<td>4 risk factors</td>
<td>443</td>
<td>51</td>
<td>11.5</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
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<td></td>
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<tr>
<td>Antidepressants</td>
<td>83,918</td>
<td>34,258</td>
<td>40.8</td>
<td>15.7</td>
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<tr>
<td>OAD (weight gain)</td>
<td>26,550</td>
<td>5,511</td>
<td>20.8</td>
<td>2.5</td>
</tr>
<tr>
<td>OAD (weight loss)</td>
<td>26,087</td>
<td>4,247</td>
<td>16.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>17,086</td>
<td>6,097</td>
<td>35.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>5,578</td>
<td>2,493</td>
<td>44.7</td>
<td>1.1</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>838</td>
<td>544</td>
<td>64.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Progestosterone</td>
<td>7,002</td>
<td>3,160</td>
<td>45.1</td>
<td>1.5</td>
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<tr>
<td>Steroids</td>
<td>45,186</td>
<td>17,770</td>
<td>39.3</td>
<td>8.2</td>
</tr>
<tr>
<td>Weight-loss agents</td>
<td>2,975</td>
<td>254</td>
<td>8.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>15,083</td>
<td>6,067</td>
<td>40.2</td>
<td>2.8</td>
</tr>
</tbody>
</table>

BMI = body mass index; HDL-C = high density lipoprotein cholesterol; kg/m² = ratio of weight in kilograms to height in meters squared; OAD = oral antidiabetic agents (insulin was included in the weight-gain agents); TG = triglycerides.
Association Between Cardiometabolic Risk Factors and Body Mass Index
Based on Diagnosis and Treatment Codes in an Electronic Medical Record Database

TABLE 2
Description of Individual and Multiple Cardiometabolic Risk Factors
Identified by Treatment, Diagnosis, or Both (n = 209,633)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Individual Risk Factors</th>
<th>Multiple Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 157,586</td>
<td>n = 52,047</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Treatment Only</td>
</tr>
<tr>
<td>Elevated Triglycerides</td>
<td>3,667</td>
<td>1,087</td>
</tr>
<tr>
<td>Low HDL-C</td>
<td>1,201</td>
<td>0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>141,852</td>
<td>13,257</td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>10,866</td>
<td>3,634</td>
</tr>
<tr>
<td>Overall</td>
<td>157,586</td>
<td>17,978</td>
</tr>
</tbody>
</table>

HDL-C = high-density lipoprotein cholesterol

Discussion

Health care payers face a lack of information, which is available to the health care provider, when attempting to identify patients with select conditions and risk factors based only on administrative claims data. In the absence of clinical data that would provide information about BMI or weight and waist circumference, it is difficult for payers to identify overweight patients who are at a high risk of poor cardiovascular outcomes and thus potential candidates for weight loss intervention.

Thus, the purpose of this work was to define a study population by means of an EMR database only by the data available in administrative claims to determine associated BMI. Our results demonstrated that certain patient characteristics could, with moderate success, identify patients at risk of having a BMI >27 kg/m² based on whether an individual has been diagnosed or treated for cardiometabolic risk factors identifiable by administrative claims. The adjusted logistic regression model in this study provides a statistically significant moderate discriminatory potential (c-statistic: 0.67) to predict patients with a BMI >27 kg/m² by cardiometabolic risk factors. In every category, patients with 1 or more cardiometabolic risk factors identified only by diagnosis or treatment indicators that are typically available in claims data were more likely (OR = 1.45-5.07) to have a BMI >27 kg/m² than were patients without those cardiometabolic risk factors. Among individual risk factors, type 2 diabetes or elevated triglyceride levels had the greatest association with a BMI >27 kg/m². The odds of having a BMI >27 kg/m² were multiplied by 2.64 for patients with type 2 diabetes and 2.21 for patients with elevated triglyceride levels, compared with patients without risk factors. Furthermore, patients with hypertension or low HDL-C had 1.91 and 1.45 times the odds of a BMI >27 kg/m², respectively, compared with patients without risk factors. This risk of having a BMI >27 kg/m² becomes more pronounced for patients with 2 or more risk factors, for whom the adjusted OR increases from 3.58 with 2 risk factors to 5.07 with 4 risk factors.

The associations between being overweight to obese and the development of hypertension and dyslipidemias identified in this study are similar to those found in prospective cohort studies, which helps validate these findings. For example, an analysis based on the Framingham Heart Study, which followed patients for up to 44 years, found that the risk of developing hypertension was more than 2.5 times as high (relative risk [RR] = 2.63, 95% CI = 2.20-3.15) for obese women (BMI of 30 kg/m² or greater) and more than 2 times as high (RR = 2.23, 95% CI = 1.75-2.84) for obese men than for women and men of normal weight. The risk of developing type 2 diabetes was 36% higher in obese women (RR = 1.36, 95% CI = 1.03-1.78) and 85% higher in obese men (RR = 1.85, 95% CI = 1.31-2.26) than for women and men of normal weight. Similarly, the San Antonio Heart Study also found an association between BMI and the development of type 2 diabetes. For each standard deviation increase in weight, the odds of developing type 2 diabetes increased 51% in women (OR = 1.51, 95% CI = 1.21-1.90) and 69% in men (OR = 1.69, 95% CI = 1.07-2.65).

Recent research (2007) has also explored the impact of body weight, alone versus as a component of metabolic syndrome, in relation to risk of incident cardiovascular disease events over a 10-year follow-up period from the Women’s Health Study. These results indicated that, among women without metabolic syndrome, there was no significant increase in RR for those who were overweight (BMI of 25-29.9 kg/m², RR = 1.08, 95% CI = 0.87-1.33) and a somewhat increased risk for those who were obese (BMI of 30 kg/m² or greater, RR = 1.58, 95% CI = 1.21-2.08). However, the risk of incident cardiovascular disease was much greater for women with metabolic syndrome (RRs of 2.40 for normal-weight women, 3.01 for women with a BMI of 25-29.9 kg/m² and 2.89 for women with a BMI of 30 kg/m² or greater).
These findings support our work in recognizing that patients who are overweight and have indicators of hypertension, dyslipidemia, or diabetes are at higher risk of cardiovascular events, and therefore may have greater benefit from weight intervention, than patients who are overweight alone. This targeted benefit can have important implications for the value of policies that restrict...
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weight-lowering medications to only patients with evidence of multiple risk factors.

From the perspective of population management, these findings may help health systems allocate resources and facilitate interventions to promote weight loss in patients with high cardiometabolic risk. We believe that this is the first study to evaluate the ability to use cardiometabolic risk factors as a predictor of whether patients are obese or overweight using only the data that would be available in a pharmacy and medical claims database. A few studies have used administrative or survey data to evaluate associations between patient demographics or cardiometabolic risk and obesity, but none of these studies evaluated whether cardiometabolic risk factors predict obesity. For example, Godley et al. evaluated the prevalence of cardiometabolic risk factors in a population of patients with both hypertension and type 2 diabetes, using claims data supplemented with medical record data for a subset of the study population; rates of obesity, dyslipidemia, and tobacco use were documented. Hollenbeak et al. and Finkelstein et al. used National Health and Nutrition Examination Survey (NHANES) data to study obesity and cardiometabolic risk. Hollenbeak et al. evaluated the predictive utility of basic demographic data in predicting components of the metabolic syndrome, including abdominal obesity, in the absence of clinical data, finding significant associations among abdominal obesity, age, and gender. Finkelstein et al. found that obesity increased the risk for the development of diabetes and hyperlipidemia.

In the present study, 50.2% (141,583) of patients whose BMI was greater than 27 kg/m² had either an ICD-9-CM diagnosis or were on treatment for 1 of the nonobesity cardiometabolic risk factors. Although a large proportion of patients with a BMI >27 kg/m² had only 1 risk factor (n=99,715; 35.4%), a substantial minority (14.8%) had 2 or more risk factors. Presence of 2 or more risk factors multiplied the odds of having a BMI >27 kg/m² by factors of 3-5. In those patients with 1 risk factor and a BMI >27 kg/m², the prevalence of hypertension (31.3%) was highest however the adjusted OR (2.64) for having a BMI >27 kg/m² was greatest in patients with type 2 diabetes. As an example, patients in a health plan with a cardiometabolic risk factor such as type 2 diabetes or dyslipidemia and a BMI >27 kg/m² may be a target for weight-loss interventions, including weight-controlling medications. A recent (June 2008) guidance from the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom recommends coverage for rimonabant as an adjunct to diet and exercise in patients who have had inadequate response to, or are intolerant of, orlistat and sibutramine and who have either a BMI of 30 kg/m² or greater and no risk factors or a BMI >27 kg/m² and at least 1 risk factor such as type 2 diabetes or dyslipidemia. The NICE guidance notes that “steatorrhea as a consequence of not adhering to dietary advice should not be considered as intolerance to orlistat,” and treatment with rimonabant should be continued beyond 6 months only if the patient has lost at least 5% of his or her initial body weight before starting rimonabant.

Recognizing the role of obesity in cardiometabolic risk, National Institutes of Health guidelines recommend treatment with a weight-loss agent for patients with a BMI of 30 kg/m² or greater without additional risk factors or with a BMI of 27 kg/m² or greater in patients with at least 1 concomitant risk factor. who have been unable to lose weight or maintain weight loss with conventional nondrug therapies. The treatment cutoff of a BMI >27 kg/m² for patients with cardiometabolic risk factors was used in this study, because in the application of these findings, all patients considered for weight-loss pharmacotherapy will have at least 1 additional cardiometabolic risk factor. The results of the present study indicate that approximately 80% of patients with 2 or more risk factors as identified by ICD-9-CM codes or national drug code numbers in an administrative claims database would be expected to have a BMI >27 kg/m². These findings, if validated by additional research, may help to support the rationale for initiating weight-loss interventions, including pharmacotherapy in patients with 2 or more cardiometabolic risk factors identified from administrative claims data.

An additional important consideration is the economic impact of potential savings from BMI reduction in patients in these various risk categories. A limitation of the EMR database is that cost data are not included. However, if the characteristics of the patients in each risk group can be matched to patients in administrative claims, the costs of each risk group can be determined and the economic impact of weight reduction to decrease risk can be measured. We are currently pursuing this work and plan to present the results in a future manuscript. Ultimately, the results from this work may have the potential to help health plans with access to only medical and pharmacy claims data to determine the potential economic benefit of weight-loss intervention in their patients with cardiometabolic risk.

Limitations
Foremost among the limitations of this study is the absence of a test of validity of the proposed method of identifying overweight and obese persons from administrative claims data only. For example, it is well known that drugs prescribed and captured in an EMR, which were the most common indication of cardiometabolic risk factors in our database, may not be purchased or used by patients. In addition, the predictive validity of our model has not been established in any population other than the sample in which the predictive weights (ORs) were calculated, and the c-statistic of 0.667 for the present sample indicated only moderate success in predicting BMI from risk factors found in EMR data. For this model to be usable by health plans, its predictive accuracy should be improved and validated in other health plan populations, perhaps by eliminating from the model risk factors that have only slight association with a BMI >27 kg/m² (e.g., low HDL-C level with no other risk factors).
Second, we did not examine the relationship of actual use of weight-loss medications and presumptive appropriate use as determined by BMI. The 2,721 overweight patients with EMR documentation of use of at least 1 weight-loss medication represented 1.0% of the patients with a BMI >27 kg/m² and 1.9% of the patients with a BMI >27 kg/m² and at least 1 cardiometabolic risk factor. Our data would have been more informative if we had stratified the use of weight-loss medications by BMI >27 kg/m² and BMI >30 kg/m².

Third, patients were selected from a population with a documented BMI measurement. Requiring a BMI value in the EMR data may have introduced bias because physicians may be more likely to measure height so that a BMI can be calculated and input by the physician or automatically calculated by the EMR in patients who are overweight or who have other cardiometabolic risk factors, compared with normal weight patients without obvious cardiovascular risk factors. Thus, our sampling method may have skewed the population to higher risk and thereby overestimated the ability to predict BMI from these associated cardiometabolic risk factors.

Fourth, although we used data elements commonly available in claims data, we did not actually obtain them from administrative claims; we obtained them from an EMR. It is unknown how well the EMR data used in the present study would translate into administrative claims stored by health plans. For example, diagnoses codes in an EMR, which document care provided to a patient, might not match the codes billed by the provider and stored in administrative claims data.

Conclusions
This study assessed the association between BMI and common cardiometabolic risk factors in the interest of developing a methodology to use administrative claims data to identify patients who may benefit from weight-loss interventions, as demonstrated by large prospective cohort studies. Further validation of the predictive value of this work may help target weight-loss interventions.

DISCLOSURES
This study was funded through an unrestricted research grant from sanofi-aventis, and Rami Ben-Joseph is an employee of sanofi-aventis.

All authors except Sameer Ghate contributed to the study concept and design. Data collection was primarily the work of Ghate with assistance from Qayyim Said. All authors contributed to data interpretation. Said did most of the work in writing and revising the manuscript, with assistance from the other authors.

REFERENCES

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Association Between Cardiometabolic Risk Factors and Body Mass Index
Based on Diagnosis and Treatment Codes in an Electronic Medical Record Database


## Cardiometabolic Risk Factors and Their Treatment or Diagnostic Indicators

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Pharmacotherapy(^a) (1 or more)</th>
<th>ICD-9-CM (1 or more)</th>
</tr>
</thead>
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<td>High triglycerides</td>
<td>Fibric acid derivatives</td>
<td>272.1 Pure hyperglyceridemia</td>
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<tr>
<td>Low HDL-C</td>
<td>Nicotinic acid derivatives</td>
<td>NA</td>
</tr>
<tr>
<td>Hypertension</td>
<td>ACE inhibitors</td>
<td>401.x Essential hypertension</td>
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<tr>
<td></td>
<td>Angiotensin II receptor antagonants</td>
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</tr>
<tr>
<td></td>
<td>Calcium channel blockers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Beta-blockers cardioselective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Beta-blockers nonselective</td>
<td></td>
</tr>
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<td>Thiazides and thiazide-like diuretics</td>
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<tr>
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<td>Vasodilators</td>
<td></td>
</tr>
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<td>ACE inhibitor and calcium channel blocker combinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ACE inhibitors and thiazide/thiazide-like</td>
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<td>Angiotensin II receptor antagonants and thiazides</td>
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</tr>
<tr>
<td></td>
<td>Beta-blocker and diuretic combinations</td>
<td></td>
</tr>
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<td></td>
<td>Vasodilators and thiazides</td>
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</tr>
<tr>
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<td><strong>Oral antidiabetic agents</strong></td>
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</tr>
<tr>
<td></td>
<td>Sulfonylureas</td>
<td>250.x2 Diabetes mellitus type 2 or unspecified type uncontrolled</td>
</tr>
<tr>
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<td>Biguanides</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thiazolidinediones</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>Alpha-glucosidase inhibitors</td>
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</tr>
<tr>
<td></td>
<td>Sulfonylurea-biguanide combinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thiazolidinedione-biguanide combinations</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) The Electronic Medical Record database includes the Medi-Span Generic Product Identifier (GPI) code for each drug in prescription orders or patient-reported medication lists; GPI codes are available from the authors by request.

ACE = angiotensin-converting enzyme; HDL-C = high-density lipoprotein cholesterol; ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification.
Estimating the Impact of Medicare Part D on the Profitability of Independent Community Pharmacies

Norman V. Carroll, PhD

ABSTRACT
BACKGROUND: Medicare Part D provides insurance coverage for prescription drugs to elderly and disabled consumers. Part D accounted for 24% of prescriptions dispensed by independent pharmacies in the first year of the program (2006). To date, the impact of Part D on independent pharmacies has been explored only in small, qualitative, or non-peer-reviewed studies.

OBJECTIVE: To develop preliminary estimates of the impact of Part D on independent pharmacies’ profitability.

METHODS: A financial model was built to examine the impact of Part D on pharmacy profitability. A key input value was the gross margin percentage for Part D; the midpoint of estimates reported in the literature was used as the base-case input value. The remaining model inputs were derived from 2 non-peer-reviewed published sources: (a) the National Community Pharmacist Association (NCPA)’s survey of independent pharmacies, which provided financial data for the year prior to Part D implementation (2005); and (b) IMS Health national market research data, which provided information about changes in prescription drug utilization from 2005 to 2006. Model estimates represented a “typical” independent pharmacy, defined using mean values for financial measures in 2005 as reported by NCPA. The model examined the impact of Part D on the proportion of prescriptions reimbursed by other sources (private third-party insurance, Medicaid, and cash payments by patients); pharmacies’ overall prescription gross margin; the number of Part D-induced prescriptions; the number of prescriptions lost to mail-order pharmacies; and net income before taxes. Key values and assumptions were subjected to one-way and probabilistic sensitivity analyses.

RESULTS: The model indicated that implementation of Part D resulted in a mean (SD) 22% (4%) decrease in net income before taxes. This change was primarily the result of an absolute 0.7% decline in the gross margin for all prescriptions. The lower overall gross margin resulted from lower reimbursement on Part D prescriptions. In the typical independent community pharmacy, Part D induced an increase in utilization of an estimated 427 prescriptions but 229 prescriptions were lost to mail-order pharmacies. The results were most sensitive to Part D reimbursement rates. Even under the most optimistic assumptions, Part D decreased net income. However, even under the least favorable assumptions, the typical independent pharmacy remained profitable.

CONCLUSION: Part D reduced the profitability of the typical independent pharmacy by an estimated mean (SD) 22% (4%) in 2006. This reduction resulted primarily from the lower Part D reimbursement rates.

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What is already known about this subject

• Part D provided reimbursement for 24% of prescriptions dispensed in independent pharmacies and 14.6% of all community and mail-order pharmacies in 2006. Part D’s effect is growing; the percentage of prescriptions covered by Part D was substantially higher in the second 6 months of 2006 than in the first 6 months.

• Part D increased prescription drug utilization only moderately in 2006, by 3.9% among Part D enrollees in an analysis of a national pharmacy chain. Utilization increases may have been moderate because only 14% of Part D enrollees paid for their drugs entirely out-of-pocket in the year before enrolling in Part D.

• A few studies have examined the impact of Part D on pharmacy gross margins. The 2007 NCPA-Pfizer Digest (for 2006 data) estimated gross margins of 19.6% for Medicaid, 18.5% for private third parties, and 16% for Part D. Winegar et al. estimated margins of 27.0% for Medicaid versus 20.4% for Part D.

What this study adds

• Part D was associated with an absolute 0.7% decline in the typical independent pharmacy’s gross margin percent for prescriptions.

• In 2006, Part D induced an estimated increase in utilization of 427 prescriptions among Part D enrollees at the typical independent pharmacy. However, 229 prescriptions were lost to mail order.

• Part D has decreased the net income of the typical independent pharmacy by a mean (SD) 22% (4%), primarily due to lower reimbursement rates.

The Medicare Part D prescription drug program was implemented on January 1, 2006. Part D was intended to fill a major gap in the Medicare program by providing insurance coverage for prescription drugs to elderly and disabled consumers, many of whom would otherwise lack coverage. The literature, while providing widely varying estimates, indicates that Part D has been successful in providing prescription drug insurance to many elderly consumers who would otherwise not be insured. For example, Neuman et al., based on a national
survey of 16,000 elderly Medicare beneficiaries, estimate that
one-third of elderly consumers lacked drug coverage in 2005
and that 61% of these enrolled in Part D plans in 2006.\textsuperscript{1} When
these results are extrapolated to the U.S. elderly population
(37 million in 2005),\textsuperscript{2} about 7.5 million elderly consumers gained
drug coverage as a result of Part D. IMS Health (IMS), based on
information from its proprietary database of over 5,400 commer-
cial and Medicare plans, estimates that 3.4 million consumers
gained access to drug coverage as a result of Part D during 2006.\textsuperscript{3}
The Kaiser Family Foundation reports that 23.9 million consum-
ers were enrolled in Part D plans as of January 2007.\textsuperscript{4}

Early estimates indicate that Part D has increased prescription
drug utilization only moderately. Yin et al. report that among
patients of a large, national, chain pharmacy, Part D-related aver-
age monthly utilization increased 1.1% in the first 5 months of
the program and 5.9% in the next 10 months.\textsuperscript{5} IMS reports that
total utilization (utilization due to Part D and all other effects)
among Part D beneficiaries increased by 3% for patients formerly
on Medicaid, 10% for those formerly enrolled in private third-
party plans, and by 26% for those with no prior insurance for
prescription drugs.\textsuperscript{6}

Part of the reason for the small increase in utilization may be
that most Part D recipients had insurance for prescription
drugs prior to enrolling in Part D. While the 26% increase in
prescription drug utilization for the group with no prior drug
insurance was substantial, IMS indicates that only 14% of Part D
enrollees paid for their drugs entirely out of pocket in the year
before enrolling in Part D. A total of 58% previously had private
third-party coverage for prescriptions and 24% were covered by
Medicaid. The remaining 4% had drug coverage from multiple
sources during the year.\textsuperscript{7}

Because of its effects on prescription sales and reimbursement,
Part D could have a major impact on the profitability of commu-
nity pharmacies in at least 3 ways. First, the limited evidence
available to date suggests that Part D is likely to result in lower
gross profit margins on prescriptions dispensed in community
pharmacies.\textsuperscript{5-9} (The gross profit on a prescription is the differ-
ence between the amount the pharmacy is reimbursed for a prescrip-
tion and the amount the pharmacy paid for the drug product
dispensed. The gross profit margin is the gross profit divided
by the amount the pharmacy was reimbursed and multiplied by
100.) Because most Part D beneficiaries had prescription drug
coverage prior to their Part D enrollment, many prescriptions
that previously were reimbursed out-of-pocket (cash), by private third-
party plans, or by Medicaid are now covered by Part D plans.
Gross margins on prescriptions reimbursed by Medicaid, cash,
or by private third parties typically yield higher margins than
those reimbursed by Part D.\textsuperscript{6,7} For example, the 2007 National
Community Pharmacist Association (NCPA) NCPA-Pfizer Digest
estimates gross margins of 19.6% for Medicaid prescriptions,
18.5% for private third-party prescriptions, and 16% for prescrip-
tions reimbursed by Part D.\textsuperscript{7} Thus, the change to Part D payment
for prescriptions that were previously, or would otherwise have
been, reimbursed by cash, Medicaid, or private third-party insur-
ance results in a lower gross margin for the pharmacy.

Second, providing prescription drug insurance to patients who
would otherwise be uninsured should increase the total volume
of prescriptions dispensed. All else equal, this change should
increase community pharmacies’ prescription sales. Third, Part D
may induce a shift of prescription volume from community phar-
macies to mail-order pharmacies. This shift would occur because
Part D plans, like most private third-party programs, usually offer
consumers substantial financial incentives to have maintenance
prescriptions dispensed through mail-order pharmacies.\textsuperscript{10-12} For
example, many third-party payers offer patients a 90-day supply
of medication through the mail-order pharmacy for the equiva-
Ient of two 30-day supply copayments. Thus, the patient pays
33% less by using the mail-order pharmacy.

A few studies have examined the effects of Part D on com-
nunity pharmacies. The Office of the Inspector General (OIG)
compared pharmacy reimbursement for Part D prescriptions
with pharmacies’ drug acquisition costs.\textsuperscript{13} The study found that
Part D reimbursement for product acquisition costs exceeded
actual pharmacy acquisition costs by an average of $9.13 (or
18.1%) per prescription. In addition, Part D paid pharmacies
an average dispensing fee of $2.27. This total reimbursement
amount represented an average gross margin of 11.40, or 18.4%,
for Part D prescriptions. Self-reported estimates from 69 of the
99 sampled pharmacies indicated average dispensing costs
of $9.13 (range $3.50 to $19.00) per prescription. OIG reports that
the estimates were based on different methods and that it “was
unable to assess the accuracy of those estimates.”

The OIG study also found that Part D dispensing fees were
about $2 less, on average, than those paid by Medicaid. This
difference in dispensing fees could partially explain why Part D
margins are lower than those paid by Medicaid. However, to fully
understand the difference in gross margins, it would be necessary
to also know how Medicaid product reimbursement compares
with Part D product reimbursement. The OIG study did not
examine the effect of Part D on pharmacy sales or the difference
between reimbursement and acquisition costs for prescriptions
reimbursed by other payers. As a result, the report provided an
incomplete picture of the effect of Part D on community pharma-
cies’ profitability.

Radford et al. examined independent pharmacists’ early (first
7 post-implementation months) experiences with Part D using
semi-structured telephone interviews conducted with 22 rural
pharmacies located in 10 states.\textsuperscript{14} Their interviews suggested
that gross margins have decreased, prescription volume has
increased, but prescription sales have remained flat. However,
this study provided qualitative results based on pharmacists’
impressions and opinions rather than specifically measuring
Part D’s effects on pharmacy profitability through examination
of financial records.
A report posted on the website of the Center for Pharmaceutical Marketing and Management at the University of Mississippi details the results of Reisetter et al.‘s study of the effects of Part D on the profits of community pharmacies. The study compared 300 pairs of matched prescriptions from 10 pharmacies located throughout the United States. One prescription from each pair was reimbursed by Part D in 2006; the matching prescription was for the same product and quantity, but reimbursed by cash, Medicaid, or a private third-party plan in 2005. The authors estimated Part D gross margins at 18.6% compared with 24.0% for prescriptions reimbursed by a combination of cash, Medicaid, and private third-party plans, and concluded that the decline in gross margin resulting from Part D implementation would decrease the net income of the typical community pharmacy by 21%. The study was limited in that it was based on a small sample of prescriptions from 10 pharmacies. Further, the analysis did not consider potential changes in prescription volume due to increased insurance coverage and mail-order usage.

Winegar and colleagues examined changes in gross margins when prescriptions switched from Medicaid to Part D coverage. Their results were based on data taken from a sample of 313 independent pharmacies in Texas. After adjusting for inflation, the average gross margin fell from 26.7% (Medicaid payment) to 20.4% (Part D payment). The gross margins in Texas independent community pharmacies for the top 5 prescription drug program sponsors ranged from 12.0% to 19.8% in 2006, prior to adjustment to 2005 dollars. The study did not consider changes in margins for cash or private third-party prescriptions. It also did not consider Part D-related changes in prescription volume.

There are at least 2 reasons that managed care organizations should be interested in the financial viability of independent pharmacies. First, over the last several years, the growth of Medicaid managed care and the implementation of Medicare Part D have substantially increased the number of managed care patients living in rural and inner city areas. Independent pharmacies are more likely to be located in these areas. Shambaugh-Miller et al. note, for example, that in 2007, 2,019 independent pharmacies were the only pharmacies in their community. Of these, 1,044 were located at least 10 miles from the next nearest pharmacy. In order to provide rural and inner-city patients with convenient access and adequate pharmacy services, managed care organizations need both urban and rural pharmacies in their networks. Second, managed care organizations’ ability to negotiate discounts on reimbursement rates with pharmacies depends on the number of pharmacies in a market area; as the number of pharmacies declines, so too does the ability of managed care organizations to negotiate discounts.

Objective

The purpose of this study was to provide a preliminary estimate of the effects of Medicare Part D on the profitability of independent community pharmacies.
were calculated by applying the conversion rates to the 2005 market share percentages. Third, IMS market share data and other sources were used to estimate other changes in utilization associated with Part D, including both increases in utilization associated with Part D coverage and decreases in community pharmacy sales associated with shifts to mail-order pharmacy use. Fourth, the gross margins for each payer type were applied to the market share data to calculate a new overall gross margin. Finally, the changes in gross margin and utilization were applied to the typical independent pharmacy’s income statement for 2005 to estimate net profit for 2006.

Data Sources
Data for the model were taken from the 2006 NCPA-Pfizer Digest (which provides data for calendar year 2005), and Medicare Part D—the First Year, a marketing research report published by IMS for calendar year 2006 data. The Digest provided financial information for a national sample of 431 independent pharmacies for 2005, the year immediately preceding implementation of Part D. (In this paper, the pharmacy described by the average values in the Digest will be referred to as the typical independent pharmacy.) The Digest provided input values for 2005 as shown in Tables 1-3. These 2005 input values included information on revenues, expenses, and average prescription price (Table 1); percent of prescriptions dispensed by payer for Medicaid, private third-party payers, and cash (Table 2); and gross margin percentages by payer (Table 3). Data for the Digest were collected by an annual survey of the owners of independent pharmacies that had been in business for at least 1 complete year. All pharmacies in the sample were “pharmacist-owned, privately held businesses.” The sample may include, in addition to traditional single-store community pharmacies, long-term care, specialty, and compounding pharmacies. The sample may also include independent pharmacies that are franchise operations or that are located in supermarkets. Owners were asked to complete and submit a questionnaire covering demographic and non-financial information and to complete forms that provided balance sheet and income statement information. Much of the data in the Digest—such as prescription and other sales, gross margins, and expenses—were calculated directly from the financial information provided. However, some data—such as estimates of prescription volume and gross margins by payer—were based on owners’ estimates. The extent to which owners based these estimates on data or judgment is not known.

Medicare Part D—the First Year (IMS) included estimates of the rates of conversion of prescriptions to Part D payment by previous payer and of increases in utilization for Part D patients by prior payer (Table 2). The IMS report was based on information from a proprietary database covering over 5,400 commercial and Medicare health plans. IMS data were based on prescriptions dispensed in both community and mail-order pharmacies.

As discussed earlier, the model assumed that Part D affected the profitability of community pharmacies in 3 ways: (a) increasing sales by providing drug insurance to previously uninsured patients, (b) decreasing sales by inducing patients to use mail-order pharmacies, and (c) decreasing gross margin. The estimation of each of these effects is discussed below.

### Estimation of Increased Prescription Utilization Due To Insurance

The number of new prescriptions that patients purchased as a result of Part D was estimated as the product of the number of prescriptions converted from other payers to Part D and the post-Part D increases in utilization by previous payer (Table 2). (The term “new” in this sense means prescriptions that the patient would not have purchased if s/he did not have Part D coverage.)

The data used to calculate conversion rates of prescriptions from cash, Medicaid, or private third-party plans to Part D payment were adapted from IMS figures. IMS reported that the percentages of prescriptions reimbursed by each payer at the end of 2005 were 16.1% paid by Medicaid, 72.0% paid by private third-party plans and 12.0% paid by cash; by the end of

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**TABLE 1** Income Statement for Typical Independent Pharmacy Before and After Implementation of Medicare Part D

<table>
<thead>
<tr>
<th></th>
<th>2005* (Model Input)</th>
<th>2006 Estimated (Model Output)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>%</td>
</tr>
<tr>
<td><strong>Sales</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td>3,210,239</td>
<td>92.1</td>
</tr>
<tr>
<td>Other b</td>
<td>275,363</td>
<td>7.9</td>
</tr>
<tr>
<td>Total</td>
<td>3,485,602</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Cost of Goods Sold</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td>2,481,749</td>
<td>77.3</td>
</tr>
<tr>
<td>Other b</td>
<td>181,251</td>
<td>65.8</td>
</tr>
<tr>
<td>Total</td>
<td>2,663,000</td>
<td>76.4</td>
</tr>
<tr>
<td><strong>Gross Margin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td>728,490</td>
<td>22.7</td>
</tr>
<tr>
<td>Other b</td>
<td>94,112</td>
<td>34.2</td>
</tr>
<tr>
<td>Total</td>
<td>822,602</td>
<td>23.6</td>
</tr>
<tr>
<td><strong>Operating Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td>693,634</td>
<td>19.9</td>
</tr>
<tr>
<td>Number Rxs dispensed</td>
<td>52,352</td>
<td></td>
</tr>
<tr>
<td>Average per-Rx price</td>
<td>$61.32</td>
<td></td>
</tr>
<tr>
<td>Average per-Rx cost of goods sold</td>
<td>$47.40</td>
<td></td>
</tr>
</tbody>
</table>

*Source: NCPA-Pfizer Digest 2006.*

b To estimate financial change associated with Part D, the model held constant (i.e., assumed no change in) nonprescription sales, cost of nonprescription goods sold, per-prescription cost of goods sold, and pharmacy operating expenses.

NCPA = National Community Pharmacists Association; Rx = prescription.
TABLE 2  Medicare Part D-Induced Increases in Prescription Volume, Prescriptions Lost to Mail Order, Net New Prescription Volume, and Payer Mix After Part Da

<table>
<thead>
<tr>
<th>Payer</th>
<th>2005 Rx Volumeb</th>
<th>% Rx Converted to Part Dc</th>
<th>Rx Converted to Part D</th>
<th>% Increase in Rx Use Due to Part Dd</th>
<th>New Rx Volume Induced by Part D</th>
<th>% of Rx Converted to Mail Order Due to Part Dc</th>
<th>Rxs Subject to Conversion to Mail Order Due to Part D</th>
<th>Rxs Lost to Mail Order</th>
<th>Net New Rx Volume Induced by Part Df</th>
<th>Total Rx Volume After Part Dg</th>
<th>Payer Mix After Part D (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>12,041</td>
<td>64.7</td>
<td>7,791</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4,250</td>
<td>8.1</td>
</tr>
<tr>
<td>Private third party</td>
<td>33,505</td>
<td>11.2</td>
<td>3,742</td>
<td>7</td>
<td>262</td>
<td>20</td>
<td>262</td>
<td>52</td>
<td>210</td>
<td>29,763</td>
<td>56.6</td>
</tr>
<tr>
<td>Cash</td>
<td>6,806</td>
<td>10.5</td>
<td>718</td>
<td>23</td>
<td>165</td>
<td>20</td>
<td>883</td>
<td>177</td>
<td>−12</td>
<td>6,088</td>
<td>11.6</td>
</tr>
<tr>
<td>Part D</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>na</td>
<td>12,449</td>
<td>23.7</td>
</tr>
<tr>
<td>Total</td>
<td>52,352</td>
<td>12,251</td>
<td>427</td>
<td>229</td>
<td>198</td>
<td>52,550</td>
<td>100.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

aNumbers shown in the table may not exactly multiply or sum to totals shown because of rounding.

bSource: NCPA-Pfizer Digest 2006.6

cSource: IMS.3 Interpreted as, for example, 64.7% of prescriptions that would have been reimbursed by Medicaid in 2005 (prior to Part D) were reimbursed by Medicare Part D in 2006. See text for explanation of how conversion percentages were estimated.

dSource: IMS.3 IMS indicated increased utilization of 3%, 10%, and 26% for Medicaid, private third-party, and cash business, respectively, from 2005 to 2006. The model assumed that 3% was attributable to non-Part D-related factors and the remaining amount was due to Part D.

eSource: IMS data10,20 and assumptions about expected rate of mail-order uptake. The model assumed mail-order participation rates of 0% for Medicaid enrollees, 20% of new volume induced by Part D for patients formerly covered by private third-party payers, and 20% of total Part D volume (new prescriptions plus prescriptions converted to Part D) for patients who formerly paid cash. See text for explanation.

fColumn represents amount of net new volume induced and paid by Part D after offsets for mail-order utilization; rows represent previous payer (e.g., a net increase of 210 new prescriptions now paid by Part D for patients who previously paid cash).

gMedicaid, private third-party payers, and cash: 2005 volume minus Rx converted to Part D (Column 1 minus Column 3). Part D: Rx converted to Part D plus net new Rx volume induced by Part D (total Column 3 plus total Column 9).

na = not applicable; NCPA = National Community Pharmacists Association; Rx = prescription.

2006 these percentages had changed to 8.7% paid by Medicaid, 65.9% paid by private third-party plans, and 10.9% paid by cash.3 However, these percentages included changes attributable both to conversion of prescriptions to Part D and to increased utilization. Because IMS reported separately both percentages of prescriptions covered and rates of increased utilization by payer, it was possible to calculate approximate conversion rates, by payer, that reflected only conversions to Part D and not increases in utilization. For example, IMS reported that the private third-party insurance share of prescriptions decreased from 72.0% in 2005 to 65.9% in 2006 and that utilization increased 10% among these patients who converted from third-party insurance to Part D. Thus:

\[
\text{Change in share} = \text{original share for payer} \times \text{conversion rate} + \text{(original share for payer} \times \text{conversion rate} \times \text{increased utilization rate)}.
\]

72.0 – 65.9 = (72.0 × conversion rate) + (72.0 × conversion rate × 0.10).

Conversion rate = 7.7%

After removing the changes due to increased utilization, the conversion rates (that is, the percentage of prescriptions by payer converted to Part D) were 44.6% for Medicaid prescriptions, 7.7% for private third-party prescriptions and 7.3% for cash prescriptions.

These figures could not be entered directly into the present study’s model because the sample of pharmacies in the IMS report included all types of community pharmacies (chain, independent, food store) as well as mail-order pharmacies. To the extent that independent pharmacies serve a higher proportion of older patients than do other types of community pharmacies, more of the independent pharmacies’ patients will be eligible for Part D. Consequently, the conversion rate of cash, Medicaid, and private third-party prescriptions to Part D payment may be higher in independent pharmacies than in the IMS sample. NCPA7 and IMS3 estimates of the proportions of prescriptions reimbursed by Part D provide support for this hypothesis. The IMS report indicates that 14.6% of prescriptions in all community and mail-order pharmacies were reimbursed by Part D in 2006.3 The NCPA Digest—which includes only independent pharmacies—indicates that, for the same time period, 24% of prescriptions were reimbursed by Part D.7
Applying the IMS conversion rates to the 2005 NCPA market share data would have resulted in an estimated market share percentage of approximately 16% for Part D. To account for the higher rate of conversions in independent pharmacies, the conversion rates reported by IMS were increased by 45% so that the percentage of prescriptions reimbursed by Part D as estimated in the model was 23.7%, approximately equal to the rate of 24% that was reported in the 2007 NCPA Digest. The conversion rates used in the study, reflecting the 45% adjustment, were 64.7% for Medicaid prescriptions, 11.2% for private third-party prescriptions, and 10.5% for cash prescriptions (Table 3). A sensitivity analysis examined the effects of varying conversion rates by 25% above and below these figures.

The IMS report provides estimates of increases in total utilization by previous payer. For example, Part D recipients who previously paid cash used 26% more prescriptions in 2006 than in 2005. The number of prescriptions dispensed annually has been increasing for many years. Consequently, it is unreasonable to assume that the total increase in utilization from 2005 to 2006 was due to Part D. To adjust for this problem, the estimates of Part-D induced increases in utilization used in the model were 3 percentage points lower than the estimates of increased utilization supplied by IMS. This adjustment was based on the following logic: IMS data indicated that utilization among Part D recipients who also received Medicaid increased by 3% from 2005 to 2006. There is no reason to expect that the switch to Part D would have increased utilization by Medicaid patients, because Part D plans do not provide more generous coverage or lower copayments than Medicaid. Consequently, the model initially assumed that Part D-related increases were 3 percentage points lower than the total increases measured by IMS.

Yin and colleagues have reported that Part D resulted in increases in utilization (pills per day) of about 1.1% for Part D eligible patients for the first 5 months of 2006 and about 5.9% for the following 7 months. These data yield an approximate 3.9% increase for the year. These results were based on data from a national chain pharmacy. Given that about 14.6% of all prescriptions were reimbursed by Part D in 2006 according to IMS data, a 3.9% increase in utilization among Part D eligible patients would equate to about a 0.57% increase in total prescription volume. A 5.9% increase for Part D patients would yield a 0.86% increase in total volume. Given this range, a sensitivity analysis in the present study examined the effects on pharmacy profitability of Part D-related increases in prescription volume from 0%-1% of total prescription volume.

### Estimation of Decreased Prescription Volume Due to Mail-Order

As indicated earlier, Part D could decrease a community pharmacy's sales as a result of increases in the number of prescriptions dispensed through mail-order pharmacies. The *Takeda Prescription Drug Benefit Cost and Plan Design Survey Report* indicated that 12% of prescriptions in plans with voluntary mail-order programs were dispensed through mail-order pharmacies in 2006 and 2007. The information in the Takeda reports is based on a national survey of benefit managers in employer-sponsored health plans.

IMS Health indicates that 22% of all non-institutional prescription sales and 7% of all non-institutional prescriptions were dispensed through mail-order pharmacies in 2006. (Non-institutional prescriptions refer to those dispensed in chain and independent pharmacies, food store pharmacies, and mail-order pharmacies; they do not include prescriptions dispensed in clinics, health maintenance organizations, hospitals, federal facilities, long-term care facility pharmacies, or by home health agencies.) Given that mail-order prescriptions are typically for 90-day supplies, and community pharmacy prescriptions are typically for 30-day supplies, it seems likely that each mail-order prescription in the IMS data would be comparable to 3 community pharmacy (30-day) prescriptions. The fact that IMS's estimates of mail-order prescription dollar sales were about 3 times higher than the estimate of numbers of mail-order prescriptions supports this hypothesis.

The estimate needed in the model was the percentage of non-institutional prescriptions dispensed by mail-order pharmacies

![Table 3: Prescription Payer Mix and Gross Margin Before [2005] and After [2006] Implementation of Medicare Part D](image)

<table>
<thead>
<tr>
<th>Payer</th>
<th>Payer Mix in 2005 (%) (of total prescriptions)</th>
<th>Average Gross Margin in 2005 (%)</th>
<th>Payer Mix in 2006 (%) (of total prescriptions)</th>
<th>Average Gross Margin in 2006 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>23.0</td>
<td>20.8</td>
<td>8.1</td>
<td>20.8</td>
</tr>
<tr>
<td>Private third party</td>
<td>64.0</td>
<td>19.3</td>
<td>56.6</td>
<td>19.3</td>
</tr>
<tr>
<td>Cash</td>
<td>13.0</td>
<td>42.8</td>
<td>11.6</td>
<td>42.8</td>
</tr>
<tr>
<td>Part D</td>
<td>0.0</td>
<td>na</td>
<td>23.7</td>
<td>18.3</td>
</tr>
<tr>
<td>Total/mean</td>
<td>100.0</td>
<td>22.7</td>
<td>100.0</td>
<td>22.0</td>
</tr>
</tbody>
</table>

*a Source: NCPA-Pfizer Digest 2006. *b The 2006 Digest reports data for the previous calendar year, 2005. Gross margins for cash payers were not reported directly in the Digest, they were calculated algebraically using the overall prescription gross margin and, for all other payers, the payer’s gross margin weighted by its market share.

c Source: Table 2.

d The gross margin for Part D is estimated as detailed in the text. Gross margins for the other payers are assumed to be the same as in 2005. The mean overall prescription gross margin is the mean of the gross margins for each payer weighted by the proportion of prescriptions reimbursed by that payer.

e The 2006 NCPA-Pfizer Digest indicated that 5% of prescriptions were reimbursed through Medicare drug discount cards in 2005. The model assumed that prescriptions reimbursed through drug discount cards were considered to be private third-party prescriptions in the model. na = not applicable; NCPA = National Community Pharmacists Association.
for private third-party plans. IMS data indicate the percentage of non-institutional prescriptions dispensed by mail-order pharmacies for all payers—cash, Medicaid, and private third-party. The following procedure was used to estimate the percentage of non-institutional prescriptions dispensed by mail-order pharmacies for private third-party plans. First, it was assumed that all mail-order prescriptions are reimbursed by private third-party plans; that is, essentially no Medicaid or cash prescriptions are dispensed by mail. Second, because mail order accounts for 22% of prescription dollar sales, it was assumed that mail order accounts for about 22% of the total number of 30-day equivalent prescriptions dispensed by all payers. Third, IMS data indicate that private third-party plans reimbursed 72% of prescriptions dispensed in 2006. Given these assumptions, it was estimated that mail order dispensed (22%/72% =) 30% of non-institutional, third-party plan prescriptions (30-day equivalents).

Based on these estimates, the model initially assumed that 20% of prescriptions dispensed for patients formerly paying cash would be dispensed through mail-order pharmacies. The figure was varied from 10% to 35% in a sensitivity analysis.

The model assumed that the extent of increased mail-order use would differ according to the patients’ source of payment prior to Part D. The financial incentive to use mail-order pharmacy usually takes the form of lower patient copayments. Copayments for low-income patients, such as those on Medicaid, are substantially lower than those for patients with higher incomes. Because copayments are lower, the financial incentives to use mail-order pharmacy would be correspondingly weaker. Further, patients enrolled in both Medicaid and Medicare (“dual-eligibles”) can change Medicare Part D plans every 30 days. Because of this policy, plans may be reluctant to allow these patients to obtain 90-day supplies of medications. Recent research based on data from the Medical Expenditure Panel Survey documents low use of mail-order pharmacies by patients with public insurance. As a result, the model assumed that no prescriptions for Medicaid patients would be dispensed through mail-order pharmacies.

A community pharmacy would be expected to lose the largest proportion of prescriptions to mail-order pharmacy for those Part D patients who previously paid cash. Prior to Part D, few, if any, of these patients’ prescriptions would be dispensed through mail-order pharmacies. After Part D, all of these patients’ prescriptions would be subject to dispensing through the mail. Thus, the model assumed that 20% of all prescriptions for Part D patients who previously paid cash would be dispensed through mail-order pharmacies. This assumption was based on the rate of 20% of all third-party prescriptions being dispensed through the mail that was discussed earlier.

A community pharmacy would be expected to experience a smaller shift of prescriptions to mail-order for Part D patients whose prescriptions were previously reimbursed by private third-party programs. These patients would have been subject to strong financial incentives to use mail-order pharmacy prior to being covered by Part D. As a result, the model assumed that any prescriptions that they chose to have dispensed in a community pharmacy before implementation of Part D would continue to be filled in a community pharmacy after implementation of Part D. However, any new prescriptions dispensed as a result of Part D coverage would be subject to dispensing through mail-order. Therefore, the model estimated community pharmacies’ loss of prescriptions to mail-order pharmacy from these patients to be 20% of any new prescription volume resulting from Part D coverage.

To sum up, the number of prescriptions lost to mail-order as a result of Part D was estimated as 20% of all Part D prescriptions dispensed for patients who previously paid out-of-pocket and 20% of new, Part D-induced prescriptions for patients who previously had private third-party coverage (Table 2).

Estimation of Change in Prescription Gross Margin Percentage
A pharmacy’s prescription gross margin percentage is determined by the relative proportion of prescriptions reimbursed by each payer—cash, Medicaid, private third-party plans, Part D—and the average gross margin percent earned on prescriptions reimbursed by each payer. To estimate the change in the typical community pharmacy’s gross margin percentage, the model first estimated the change in the percentage of prescriptions covered by each payer after implementation of Medicare Part D (Tables 2 and 3).

The model initially used a gross margin percent of 18.5% for Part D prescriptions. This approximates the gross margins estimated in studies by the OIG and Reisetter et al. A sensitivity analysis examined the effects of varying the gross margin paid by Part D plans from 16% to 21%. The lower margin—16%—is the margin reported in the 2007 NCPA-Pfizer Digest for Part D prescriptions; the higher margin—21%—is slightly above that estimated by Winegar et al.

The typical community independent pharmacy’s prescription gross margin percentage, after implementation of Medicare Part D, was then calculated as the average of the gross margins earned from each payer weighted by the proportion of the pharmacy’s prescription volume represented by each payer (Table 3).

Estimation of Overall Effect on Profitability
The average prescription price after implementation of Part D was estimated based on the new gross margin percentage, assuming no change to the per-prescription cost of goods sold (Table 4). Post-implementation prescription volume (number of prescriptions) was calculated as pre-implementation (2005) prescription volume plus the Part D-induced increase in prescription volume less the Part D-induced loss of prescriptions to mail-order pharmacies (Tables 2 and 4). Post-implementation prescription
The model assumed no Part D-related change in operating expenses. The model estimated that 23.7% of prescriptions dispensed by the typical independent community pharmacy were reimbursed by Medicare Part D in 2006 (Tables 2 and 3). The vast majority of these prescriptions would have otherwise been reimbursed estimate from the model. Probabilistic sensitivity analyses were used to consider the effects of uncertainty in multiple variables simultaneously and to incorporate the probabilities associated with the uncertainty in each variable. One-way sensitivity analyses examined the effects of assumptions about gross margin, rates of conversion to Part D from other reimbursement sources, change in total prescription volume related to Part D, and the mail-order conversion rate, using the input values shown in Table 5. The variables, values, and probabilities used in the probabilistic sensitivity analysis are shown in Table 6. The probabilistic sensitivity analysis was conducted using a Monte Carlo simulation with 1,000 iterations using Microsoft Excel 2003 (Microsoft, Redmond, Washington, 2003).

## Results

The model estimated that 23.7% of prescriptions dispensed by the typical independent community pharmacy were reimbursed by Medicare Part D in 2006 (Tables 2 and 3). The vast majority of these prescriptions would have otherwise been reimbursed

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**TABLE 4** Calculation of Average Prescription Price, Prescription Sales, and Prescription Cost of Goods Sold After Part D Implementation

<table>
<thead>
<tr>
<th>Post-Implementation Average Prescription Price</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Part D average prescription price</td>
<td>$61.32</td>
</tr>
<tr>
<td>Pre-Part D average prescription gross margin percent</td>
<td>22.7%</td>
</tr>
<tr>
<td>Pre-Part D average prescription gross margin dollars</td>
<td>$13.92</td>
</tr>
<tr>
<td>Pre-Part D average prescription price</td>
<td>$61.32</td>
</tr>
<tr>
<td>Pre-Part D average prescription gross margin dollars</td>
<td>$13.92</td>
</tr>
<tr>
<td>Average prescription cost of goods sold</td>
<td>$47.40</td>
</tr>
<tr>
<td>Average prescription cost of goods sold</td>
<td>$47.40</td>
</tr>
<tr>
<td>Post-Part D prescription gross margin percent</td>
<td>22.7%</td>
</tr>
<tr>
<td>Post-Part D average prescription price</td>
<td>$60.73</td>
</tr>
</tbody>
</table>

**Post-Implementation Prescription Sales**

| Pre-Part D prescription volume (# of prescriptions) | 52,352 |
| Part D-induced change in prescription volume      | 1,998 |
| Post-Part D prescription volume                   | 52,350 |
| Post-Part D average prescription price            | $56.73 |
| Post-Part D prescription sales                    | $3,191,392 |

**Post-Implementation Prescription Cost of Goods Sold**

| Pre-Part D prescription volume                   | 52,352 |
| Part D-induced change in prescription volume     | 1,998 |
| Post-Part D prescription volume                   | 52,350 |
| Average prescription cost of goods sold          | $47.40 |
| Total prescription cost of goods sold            | $2,490,903 |

---

### Formulae

\[
\text{GMD} = \frac{\text{GMP} \times \text{COGS}}{(1 – \text{GMP})} = \frac{(0.220 \times 47.40)}{(1 – 0.220)} = \$13.37.
\]

where GMD = post-Part D gross margin dollars, GMP = post-Part D gross margin percent, and COGS = cost of goods sold (per prescription). Total of $60.77 is 0.04 different from the figure reported due to rounding error. Assumes that the average prescription cost of goods sold does not change from pre- to post-implementation. Lower prescription price reflects only the change in gross margin percent.

---

**TABLE 5** One-Way Sensitivity Analyses of Effects of Medicare Part D on the Net Profit of the Typical Independent Community Pharmacy

<table>
<thead>
<tr>
<th>Variable</th>
<th>Net Income ($)</th>
<th>Change From Pre-Part D Net Income ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part D gross margin %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>77,131</td>
<td>51,837</td>
</tr>
<tr>
<td>17</td>
<td>86,702</td>
<td>42,286</td>
</tr>
<tr>
<td>18.5*</td>
<td>101,167</td>
<td>27,801</td>
</tr>
<tr>
<td>19</td>
<td>106,018</td>
<td>22,950</td>
</tr>
<tr>
<td>21</td>
<td>123,571</td>
<td>3,397</td>
</tr>
<tr>
<td>Conversion rates as % of IMS Health adjusted estimates*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75</td>
<td>108,121</td>
<td>–20,847</td>
</tr>
<tr>
<td>100*</td>
<td>101,167</td>
<td>–27,801</td>
</tr>
<tr>
<td>125</td>
<td>94,250</td>
<td>–34,718</td>
</tr>
<tr>
<td>Part D-related change in prescription volume (as % of total prescription volume)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>99,058</td>
<td>–29,101</td>
</tr>
<tr>
<td>0.38*</td>
<td>101,167</td>
<td>–27,801</td>
</tr>
<tr>
<td>0.50</td>
<td>101,167</td>
<td>–27,801</td>
</tr>
<tr>
<td>1.00</td>
<td>104,659</td>
<td>–24,309</td>
</tr>
<tr>
<td>Mail order conversion rate %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>102,386</td>
<td>–26,582</td>
</tr>
<tr>
<td>20*</td>
<td>101,167</td>
<td>–27,801</td>
</tr>
<tr>
<td>30</td>
<td>99,948</td>
<td>–29,029</td>
</tr>
<tr>
<td>35</td>
<td>99,339</td>
<td>–29,629</td>
</tr>
</tbody>
</table>

*Indicates the value used in the base-case analysis.

*b The adjusted IMS Health estimates of conversion rates by payer are shown in Table 2. The adjustment amounts and rationale are discussed in the text.
by Medicaid, private third-party plans, or cash. The change in payer mix, combined with the lower gross margin on Part D prescriptions, resulted in an estimated decrease in the typical independent community pharmacy’s gross margin from 22.7% in the year before implementation of Part D to 22.0% in the year following implementation (Table 3).

The model estimated that implementation of Part D resulted in covered patients using an additional 472 prescriptions (Table 2). However, an estimated 229 prescriptions converted to or induced by Part D that otherwise would have been dispensed by the community pharmacy were instead dispensed through mail-order pharmacies. Thus, the typical independent community pharmacy’s net Part D-induced increase in volume was 198 prescriptions per year. The typical pharmacy’s estimated total prescription volume after Part D was 52,550. Thus, Part D induced an increase in prescription volume of 0.38% (198/52,353).

As a result of the effect of the decreased gross margin for Part D prescriptions, along with the small net increase in prescription sales, the typical pharmacy’s estimated prescription sales decreased by $18,647, from $3,210,239 to $3,191,592, as a result of Medicare Part D (Table 1). The pharmacy’s cost of goods sold increased by $9,154 as a result of dispensing an additional 198 prescriptions. The net effect was a decrease of $27,801, or 21.6%, in the pharmacy’s pretax net income. Thus, lower reimbursement rates from Part D plans had a much greater effect on pharmacy profits than did either the increase in utilization resulting from increased insurance coverage or the change in use of mail-order pharmacies.

### Sensitivity Analysis

The results of one-way sensitivity analyses are shown in Table 5. Within the ranges tested, the factor with the greatest effect on profitability was the gross margin earned on Part D prescriptions. If Part D plans yielded a 16% gross margin, the typical pharmacy’s net income would have declined by $51,837 in 2006; if Part D plans yielded a 21% gross margin, the typical pharmacy’s net income would have declined by only $3,397. The effects of variations in the rate of mail-order usage, conversion of prescriptions to Part D, and increased utilization induced by Part D were much smaller for the ranges tested.

The probabilistic sensitivity analysis (results not shown in tables) indicated that the typical pharmacy’s net income would decline by a mean (SD) of $27,651 ($5,310), approximately 22% (4%), per year as a result of Part D. The 25th, 50th, and 75th quartiles for change in net income were $–30,348, $–27,801, and $–22,653. The minimum and maximum values were $–39,151 and $–16,991. The latter figure indicated that even under the most favorable assumptions, the typical pharmacy’s net income declined as a result of Part D. The analysis also estimated a mean (SD) net income of $101,414 ($5,420) and 25th, 50th, and 75th percentiles of $98,620, $101,167, and $106,315. Minimum and maximum net incomes were $89,817 and $111,977. The minimum value suggests that even under the least favorable conditions, the typical independent pharmacy remained profitable.

### Discussion

The financial model developed in this study estimated that the typical independent, community pharmacy realized a mean (SD) 22% (4%) decline in net income as a result of Medicare Part D. The model examined 3 ways that Part D might affect pharmacy profitability: increased sales resulting from greater utilization induced by Part D coverage, reduced gross profit margins on prescriptions converted from other payers to Part D, and decreased sales from increased use of mail order among Part D recipients. The model indicated that increased insurance coverage resulted in only a small increase in prescription utilization, probably because a large majority of Part D recipients had prescription coverage before joining Part D. IMS estimated that 86% of Part D enrollees had some type of prescription insurance before enrolling in Part D. Neuman et al. estimated that two-thirds of the elderly had prescription insurance before the implementation of Part D.

The model also indicated that increased use of mail-order pharmacies did not have a major impact on community pharmacy profits. This outcome was likely a result of several factors: low use of mail-order pharmacies among Medicaid patients, the small effect of Part D in inducing new prescription use, and the relatively small number of previously cash-paying patients that enrolled in Part D.

The factor having the greatest impact on pharmacy profitability was the decrease in gross margin from lower Part D

---

#### Table 6

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value of Variable</th>
<th>Probability Associated With Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part D gross margin</td>
<td>16%</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>18.5%</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>21%</td>
<td>0.25</td>
</tr>
<tr>
<td>Conversion rate (% of IMS estimate) a</td>
<td>75%</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>125%</td>
<td>0.25</td>
</tr>
<tr>
<td>Part-D related change in prescription volume (% of total prescription volume)</td>
<td>0%</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>0.38%</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>1.00%</td>
<td>0.25</td>
</tr>
<tr>
<td>Mail order conversion rate (% of prescriptions)</td>
<td>10%</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>20%</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>35%</td>
<td>0.25</td>
</tr>
</tbody>
</table>

*a The IMS estimates of conversion rates by payer are shown in Table 2.*
reimbursement rates. This outcome occurred because the great majority of prescriptions dispensed for Part D, over 98% based on the estimates in Table 2, would have been reimbursed by other payers at higher gross margins had Part D not been implemented.

Sensitivity analyses revealed no scenario—over the ranges tested—in which net profit increased as a result of Part D. Even the best-case scenario produced a small negative effect on net profit. Model results were not sensitive, over the ranges tested, to the rate of mail-order prescription use, the rate at which prescriptions were converted to Part D from other payers, or increased utilization induced by Part D coverage. The insensitivity to mail-order usage was probably a result of the small increase in prescription volume related to Part D and the low rate of conversion of cash to Part D prescriptions. Because estimated volume increased only minimally, even Part D mail-order usage of 35% would have small effects on profitability.

The model was much more sensitive to variations in Part D reimbursement rates. Each 1 percentage point decrease in the gross margin earned on Part D prescriptions decreased the pharmacy's profit by about $9,600 per year (Table 5). The trend in pharmacy reimbursement in private plans has been negative over the past decade.10 The results of this analysis suggest increasing pressure on pharmacy profits from Part D in the future.

While the results indicated that the typical pharmacy suffered a substantial reduction in profits as a result of Part D, they also indicated that the loss was not large enough to put the typical pharmacy out of business in any of the scenarios modeled. However, because no information on the distribution of pharmacies by profitability was available, it was not possible to estimate the number of pharmacies that would be put out of business by Part D.

The model's results apply to the “typical” or “average” independent community pharmacy. Pharmacies with substantial populations of elderly patients whose prescriptions were reimbursed by cash or Medicaid before implementation of Part D would have seen much larger negative effects. Pharmacies in rural or inner city areas, which dispense greater proportions of cash and Medicaid prescriptions, would be particularly hard hit by Part D.

The results of the present study also underscore the growing importance to community pharmacies of finding non-product related sources of revenue. Over the last 2 decades, the proportion of prescriptions reimbursed by third-party payers has increased as the rates of reimbursement from these payers have decreased.10,26 The conversion of elderly, cash-paying consumers to third-party coverage under Part D was only the latest step in this trend. The trend clearly indicates that dispensing prescriptions will continue to be less and less profitable for community pharmacies, and that the future of community pharmacy lies less in dispensing and more in patient-care services such as medication therapy management.

Limitations
The results of the study are limited in that they are based on a model. To the extent that the data used in the model are not representative, the study may provide misleading results. Most of the data used in the study came from sources that were not peer-reviewed (IMS and the NCPA-Pfizer Digest). Further, estimates of payer mix and gross margins by payer were based on owners' self-reports. It is not known whether these data were based on judgment or actual financial information. Further, the main data sources for the study, IMS and the Digest, provided point estimates of input values without providing measures of error. On the other hand, the data used in the model came from a national sample of 431 independent community pharmacies (as reported in the Digest) and a large, national study of Part D-related changes in prescription use as reported by IMS, a commonly cited reference source. Data from the Digest have been used extensively in studies examining the finances of independent community pharmacies, and IMS is a world-wide leader in the provision of prescription use data. Finally, the model included extensive sensitivity analyses to examine the effects of variations in model inputs.

The model's results are based on a number of assumptions. The major assumptions were based on estimates taken from the literature and were examined in sensitivity analyses. The results were relatively insensitive to variations in all of the parameters examined except Part D reimbursement rates. However, even the most optimistic assumption about Part D reimbursement showed a decrease in the typical pharmacy's net income.

Much of the decrease in profitability associated with Part D resulted from lower gross margins paid by Part D compared with other payers. Part of the difference in gross margins between Part D and other payers could be attributable to different rates of generic drug use, which would lead to different prescription gross margins because pharmacies earn substantially greater margins on generic drugs than on branded drugs. For example, Winegar et al. found gross margins for brand-name drugs of 8.7% for Medicaid and 8.3% for Part D. For generics, margins were 39.9% for Medicaid versus 29.5% for Part D.8 Data provided in the OIG report indicate gross margins of 8.9% for brands versus 48.0% for generics.13 (These figures are not reported by OIG but can be calculated from the acquisition cost-reimbursement cost differences and dispensing fees that are reported.) However, the evidence to date indicates that generic usage rates in Part D are similar to, or slightly higher than, those in commercial or Medicaid plans. Winegar et al. indicate that use of generics was not significantly different between Medicaid and Medicare patients in their study.8 Wolters Kluwer reports that by January, 2007, 63% of Part D claims were dispensed with generics as compared with 59% of private third party plans.27 The OIG report indicates similar rates of generic drug usage between Part D and Medicaid plans.13 Thus, it seems unlikely that margin differences between Part D and other payers result from differing rates of generic drug use.
The payer mix predicted by the model for 2006 differed from the actual payer mix reported in the 2007 NCPA-Pfizer Digest. The predicted and NCPA-reported percentages of prescriptions by payer were, respectively, 23.7% and 24% for Part D, 11.6% and 9% for cash, 56.6% and 52% for private third party, and 8.1% and 15% for Medicaid. While this discrepancy may appear to be a significant limitation, it is probably not reasonable to expect that the 2 sources would provide the same estimates. The model assumed that the only change in the pharmacy environment between 2005 and 2006 was the implementation of Part D. The NCPA estimates, which are based on real-world data and conditions, reflected all changes in the pharmacy environment. These included, for example, changes in Medicaid eligibility requirements, changes in employers’ willingness to offer private coverage for drugs, increases in patient cost sharing, changes in reimbursement rates of other third-party payers, and changes in competition such as the Wal-Mart $4 generic program.

As discussed in the Methods section, the model assumed that no Part D prescriptions for Medicaid patients would be dispensed through mail-order pharmacies. To the extent that Medicaid patients did use mail-order pharmacies, the negative effects on pharmacy profitability would be larger than estimated by the model. However, given the historically low use of mail order in public insurance programs and the lower copayments charged to Medicaid patients (compared with non-Medicaid patients) in Part D plans, it seems unlikely that mail-order use would constitute a sizeable proportion of total Part D utilization by Medicaid patients.

■ Conclusions

A financial model based on a national sample of independent community pharmacies indicated that Part D had a substantial and negative effect on the profitability of community pharmacies. This outcome has resulted primarily from the lower reimbursement rates that pharmacies receive for Part D prescriptions. However, the typical pharmacy remained profitable even in the worst case scenario.

REFERENCES


Physicians’ Opinions About Responsibility for Patient Out-of-Pocket Costs and Formulary Prescribing in Two Midwestern States

Shamima Khan, MBA, PhD; Robert Sylvester, PharmD; David Scott, MPH, PhD; and Bruce Pitts, MD, MBA

ABSTRACT

BACKGROUND: Multi-tier copayment designs in pharmacy benefit plans are intended to steer patients and prescribers to preferred drug therapies that have lower out-of-pocket costs for patients.

OBJECTIVE: To describe and assess physicians’ prescribing experiences and opinions in a multi-tier, primarily 3-tier formulary environment in 2 Midwestern states.

METHODS: This was a cross-sectional survey of physicians practicing in either Minnesota or North Dakota. A packet consisting of a survey instrument, a cover letter, and a postage-paid return envelope was mailed to a random sample of 690 physician members of the Minnesota Medical Association (n = 460, 5.1% of members) or the North Dakota Medical Association (n = 230, 25.6% of members). Surveys were mailed between March and May 2006. Nonresponders were mailed up to 2 additional surveys. Survey items included practice specialty, sources used to obtain drug information, perceived importance of cost containment actions (e.g., prescribing drug with lowest total cost, prescribing drug that minimizes patient out-of-pocket cost), and how often the physician was personally aware of the following when writing a prescription: identity of the patient’s insurer, patient’s pharmacy benefit structure, preferred medications on the insurer’s formulary, patient’s copayment (out-of-pocket cost) responsibility, and list price of the medication.

RESULTS: The survey response rate was 49.8% (296 of 594). The results were as follows: 93.5% of respondents agreed that it was important to prescribe the drug that would minimize the patient’s out-of-pocket costs, 73.2% agreed that it was important to discuss out-of-pocket medication costs with patients, 81.8% of respondents agreed that it was important to prescribe the drug with the lowest total costs, and 33.3% of physicians believed that it was their responsibility to prescribe a preferred (formulary) medication. According to the survey, 61.6% of respondents were rarely or never aware of their patient’s copayment amounts, and 42.4% were rarely or never aware of the list price of the medication. Physician specialty was associated with the awareness of the identity of the patient’s insurer (generalists, 41.1% vs. specialists, 19.2%; P = 0.001) and use of personal digital assistant (PDA) when prescribing (generalists, 38.9% vs. specialists, 21.1%; P = 0.005).

CONCLUSION: Physicians who responded to this survey believed that it was important to prescribe drugs that would minimize patients’ prescription copayments, but they were often unaware of the preferred medications on the formulary, the patients’ copayment amounts, or the price of the drugs prescribed.

What is already known about this subject

• Surveys of California physicians document that, in 3-tier formulary benefit plans, patients’ potential out-of-pocket cost savings may often go unrealized because a majority of physicians (62%-70%) reported never or seldom having knowledge of a patient’s out-of-pocket expenses.
• Physicians tend to depend on pharmacists either to communicate patients’ medication preferences or to help patients manage out-of-pocket medication costs. In a survey of physician leaders in California, 68% of respondents agreed that it was the pharmacist’s responsibility to identify nonpreferred medications.
• In a survey of California Medical Association members, 53% and 33% of respondents reported being familiar most or all of the time with patients’ insurers and preferred formulary options, respectively.

What this study adds

• A vast majority (82%) of the physicians in this study believed that it was important to prescribe the drug that would lower total costs, and 94% believed that it was important to prescribe a medication that would reduce patients’ copayments. However, only 33% of the physicians believed that it was their responsibility to prescribe preferred medications.
• Physician knowledge of a patient’s prescription copayment varies from region to region; 53% of California physicians reported being always or often aware of a patient’s insurer, compared with only 35% of physicians in Minnesota and North Dakota.
• Physician specialty was associated with awareness of the identity of the patient’s insurer (generalists, 41.1% vs. specialists, 19.2%; P = 0.001) and use of a personal digital assistant (PDA) when prescribing (generalists, 38.9% vs. specialists, 21.1%; P < 0.001).

The percentage of the health care budget spent on medications is a growing concern in the United States. To constrain prescription drug costs, health plans have instituted incentive-based, tiered copayment pharmacy benefit plans. The Medicare Modernization Act (MMA) calls for the implementation of tiered pharmacy benefit plans that lower
patient payments for prescriptions filled with preferred drugs. In recent years, both the percentage of Americans enrolled in multi-tier copayment plans and the financial incentives in these pharmacy benefit plans have increased considerably. As of 2005, 70% of covered workers were enrolled in 3-tier copayment plans, compared with only 8% in 1998. Copayments or out-of-pocket costs for nonpreferred drugs have increased substantially in the last few years from averages of $25 in 2002 to $35 in 2005.

Studies of 3-tier formulary benefit plans suggest that patients' out-of-pocket cost savings often go unrealized because many physicians lack the knowledge to help patients minimize their prescription copayments. Researchers also have evaluated the impact of higher prescription drug costs on medication compliance. Higher copayments and lack of prescription drug coverage have been associated with decreased patient medication compliance in some studies, and research suggests that physicians often lack the time to address issues related to copayment and subsequent medication noncompliance at the time of prescribing. For example, using a statistical model based on a cross-sectional analysis of claims data for patients who initiated cholesterol lowering therapy, Goldman et al. reported that, for each $10 increase in copayment, average compliance in a plan year was predicted to drop 5 percentage points. Zhang et al. reported that, in 3-tier formulary benefit plans, patients' potential out-of-pocket cost savings may often go unrealized because many physicians (62%-70%) reported never or seldom having knowledge of a patient’s out-of-pocket expenses.

Little is known about the challenges that physicians face when prescribing in regions where numerous prescription benefit plans provide coverage with multi-tier copayments. Recent studies conducted in California indicate that physicians lack the knowledge to help patients manage their prescription copayments and often depend on pharmacists to serve as the patient's financial advocate. However, these studies may not represent physician prescribing experience in other states because of differences in the prescribing environment. For example, a study of physicians practicing in California may underestimate the challenges of prescribing in a multi-tier formulary environment because staff-model health maintenance organizations (HMOs) comprise a substantial market share in California, and these physicians are subject to only 1 drug formulary. Also, the concentration of market share in a few HMOs may limit the number of competing formularies. Shrank et al. reported that 40% of responding physicians in California indicated that they prescribe from 0 to 1 formularies. Additionally, Shrank et al. (2005 and 2006) documented that, in 3-tier formulary benefit plans, patients' potential out-of-pocket cost savings may often go unrealized because many physicians (62%-70%) reported never or seldom having knowledge of a patient's out-of-pocket expenses.

The present study was conducted to describe and assess physician prescribing experiences in a prescribing environment different than in California. Physicians in 2 Midwestern states with patients enrolled in numerous multi-tier copayment formulary plans were surveyed. The survey also included questions about Medicare Part D, because the MMA promoted tiered pharmacy benefit plans in which patient copayments are lower for preferred than for nonpreferred drugs.

Minnesota and North Dakota are upper Midwestern states. In 2006, the majority (72%) of the population in Minnesota resided in urban areas, whereas in North Dakota, a majority (53%) resided in rural areas. Other pertinent information about Minnesota and North Dakota is included in Table 1. To achieve the objective of this study, we collected information about physicians' beliefs or opinions on prescribing and drug costs, the challenges that physicians face when prescribing in a multi-tier formulary environment, and their use of information technology.

### TABLE 1 Health Care Expenditures and Utilization Characteristics for North Dakota and Minnesota

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MN</td>
<td>$29,524</td>
<td>8%</td>
<td>$5,795</td>
<td>51,717,784</td>
<td>10</td>
<td>14</td>
</tr>
<tr>
<td>ND</td>
<td>$3,693</td>
<td>7%</td>
<td>$5,283</td>
<td>3,309,159,973</td>
<td>11</td>
<td>539</td>
</tr>
<tr>
<td>U.S.</td>
<td>$1,551,255</td>
<td>6%</td>
<td>$5,808</td>
<td>6,586,945</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

*Source: The Henry Kaiser Family Foundation. Managed Care and Health Insurance.*

HMO = health maintenance organization; MN = Minnesota; ND = North Dakota, U.S. = United States.
Physicians’ Opinions About Responsibility for Patient Out-of-Pocket Costs and Formulary Prescribing in Two Midwestern States

Methods

Study Sample

A packet consisting of a survey instrument, a cover letter, and a postage-paid return envelope was mailed to a random sample of 690 physician members of the Minnesota Medical Association (n = 460) or the North Dakota Medical Association (n = 230). According to the Minnesota Medical Association, there are 12,350 licensed physicians practicing in Minnesota, and 9,000 (72.9%) are members of the state medical association. The Minnesota Board of Medical Practice acknowledges that an undetermined number of licensed physicians do not directly care for patients. According to the North Dakota Medical Association, there are 1,357 licensed physicians practicing in North Dakota, and 898 (66.2%) are members of the state medical association. The Minnesota Board of Medical Practice acknowledges that an undetermined number of licensed physicians do not directly care for patients. According to the North Dakota Medical Association, there are 1,357 licensed physicians practicing in North Dakota, and 898 (66.2%) are members of the state medical association (Figure 1).

Surveys were mailed out between March and May 2006. Nonresponders received up to 2 additional mailed surveys. Follow-up post card reminders were mailed approximately 2 weeks after the first and second survey mailings. Approximately 2 weeks after the last survey mailing, nonresponders were contacted by phone, and we sent an additional survey if requested. Phone surveys were conducted for physicians who indicated this preference. The study was approved by the North Dakota State University Institutional Review Board.

Survey Design

The survey was adapted from an instrument developed by Shrank et al. This modified instrument was pilot tested on 7 practicing physicians in Minnesota and North Dakota, and the survey was refined based on their responses. Major differences between this modified instrument and the instrument used by Shrank et al included the addition of open-ended comment items and questions about (a) Medicare Part D, (b) knowledge of the national average price of the top 10 selling drugs, and (c) exposure to cost-effective prescribing in medical school and residency training. The final survey consisted of 43 items dealing with physicians’ opinions (beliefs) about prescribing and drug costs. Other questions included practice specialty, sources used for drug information, perceived importance of cost containment actions (e.g., prescribing drug with lowest total cost, prescribing drug that minimizes patient out-of-pocket cost), and how often the physician was personally aware of the following when writing a prescription: identity of the patient’s insurer, patient’s pharmacy benefit structure, preferred medications on the patient’s formulary, patient copayment responsibility, and list price of the medication. Survey responses specific to Medicare Part D have been published as a separate manuscript and are not included in this article. The survey included open-ended, multiple-choice, and 5-point Likert scale questions. A complete copy of the survey is available upon request to the corresponding author.

Data Analysis

Descriptive statistics were used to present the characteristics of the respondents and the primary variables of interest. Physicians whose medical specialties were emergency medicine, family practice (including geriatric), general practice, gynecology, internal medicine (including geriatric), obstetrics and gynecology, obstetrics, and pediatrics were considered to be generalists. Physicians reporting any other medical specialties were considered to be specialists.

The primary variables of interest were physicians’ beliefs or opinions about prescribing and drug costs, awareness of patients’ prescription copayments at the time of prescribing, awareness of the determinants of those costs (e.g., insurers, formularies, pharmacy benefit structures) and use of information technology. Pearson chi-square analyses were performed to assess associations between outcome measures and independent variables using SAS version 9.1 (SAS Institute Inc., Cary, NC). Statistical significance was set at $P < 0.05$. We also ascertained the internal consistency (reliability) of the survey instrument for all the questions that included a Likert scale response, using Cronbach’s alpha.

Of note, the study sample was a stratified random sample in that 5.1% of the Minnesota and 25.6% of the North Dakota medical association members were selected for study. This design was used to ensure adequate representation from both states.
To ascertain the possible effect of this sampling design on study results, we performed a comparison of Minnesota and North Dakota physicians on key outcome variables. These key outcome variables were (a) importance of prescribing the drug that will minimize patients’ out-of-pocket cost, (b) importance of prescribing the drug with the lowest total cost, (c) perceived responsibility to prescribe preferred medications, (d) awareness of the preferred medications on the insurer’s formulary, (e) identity or name of the patient’s insurer, and (f) use of personal digital assistant (PDA) or computer order entry at the time of prescribing.

■ Results

Survey Response

Of 690 total surveys mailed, 1 was returned from a nonphysician and 42 others were determined to have wrong addresses. Additionally, 36 addresses from nonresponding physicians were deleted because phone numbers were not available and the physicians could not be contacted. A total of 17 respondents were deleted from the denominator because these physicians either did not make any decisions about prescription drugs (n=11) or no longer practiced medicine (n=6). The final sampling frame included 594 physicians (Figure 2). The overall response rate, including 2 phone surveys, was 49.8% (296 of 594), including 172 of 384 (44.8%) physicians from Minnesota, 123 of 210 (58.6%) physicians from North Dakota, and 1 physician who did not indicate the state in which he or she practiced medicine.

Characteristics of respondents are shown in Table 2. The age and sex of responding physicians in this sample were similar to national averages. Of 284 respondents who reported the number of formularies from which they prescribe, 34 (12.0%) reported prescribing from 0 to 1 formularies, 56 (19.7%) from 2 to 5 formularies, 74 (26.1%) from 6 or more formularies, and 120 (42.3%) from an unknown number of formularies.

Physicians’ Opinions About Prescribing, Drug Costs, and Prescribing Challenges

According to the survey, 82% of the responding physicians agreed that it was important to prescribe the drug with the lowest total cost (Table 3). Although an overwhelming majority (93.5%) of physicians believed that it was their responsibility to prescribe drugs that would minimize their patients’ copayments, only 33.3% believed that it was their responsibility to prescribe preferred formulary medications.

More than one-third (35.4%) of the physicians indicated that they were often or always aware of the identity of their patient’s insurer. However, fewer physicians indicated awareness of list
Physicians’ Opinions About Responsibility for Patient Out-of-Pocket Costs and Formulary Prescribing in Two Midwestern States

TABLE 2  
Physician and Practice Characteristics

<table>
<thead>
<tr>
<th>Characteristic (n)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age in years (n = 283)</td>
<td>48 (9)</td>
</tr>
<tr>
<td>Mean (SD) prescriptions per day (n = 291)</td>
<td>21.96 (17.8)</td>
</tr>
<tr>
<td>% (n) Male gender (n = 288)</td>
<td>68.1% (196)</td>
</tr>
<tr>
<td>Physician Specialty (n = 294)</td>
<td></td>
</tr>
<tr>
<td>Generalist</td>
<td>73.1% (215)</td>
</tr>
<tr>
<td>Specialist</td>
<td>26.9% (79)</td>
</tr>
<tr>
<td>Practice Location (n = 271)</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>71.3% (194)</td>
</tr>
<tr>
<td>Minnesota</td>
<td>70.0% (112)</td>
</tr>
<tr>
<td>North Dakota</td>
<td>73.9% (82)</td>
</tr>
<tr>
<td>Rural</td>
<td>28.3% (77)</td>
</tr>
<tr>
<td>Minnesota</td>
<td>30.0% (48)</td>
</tr>
<tr>
<td>North Dakota</td>
<td>26.1% (29)</td>
</tr>
<tr>
<td>Practice Size (n = 283)</td>
<td></td>
</tr>
<tr>
<td>Small (1-4 physicians)</td>
<td>15.2% (43)</td>
</tr>
<tr>
<td>Medium (5-150 physicians)</td>
<td>60.8% (172)</td>
</tr>
<tr>
<td>Large or very large (more than 150 physicians)</td>
<td>24.0% (68)</td>
</tr>
<tr>
<td>Information Technology and Formularies</td>
<td></td>
</tr>
<tr>
<td>Use of computer order entryb (n = 290)</td>
<td>39.3% (114)</td>
</tr>
<tr>
<td>Use of PDA for prescribingb (n = 289)</td>
<td>33.9% (98)</td>
</tr>
<tr>
<td>Use of Internet when prescribingb (n = 295)</td>
<td>22.4% (66)</td>
</tr>
<tr>
<td>Use of no information technologiesd</td>
<td>31.1% (88)</td>
</tr>
<tr>
<td>Uses any information technology (n = 286)</td>
<td>69.2% (198)</td>
</tr>
<tr>
<td>Number of formularies prescribed from (n = 284)</td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>12.0% (34)</td>
</tr>
<tr>
<td>2-5</td>
<td>19.7% (56)</td>
</tr>
<tr>
<td>6 or more</td>
<td>26.1% (74)</td>
</tr>
<tr>
<td>Unknown</td>
<td>42.3% (120)</td>
</tr>
</tbody>
</table>

a Number of responses to the item of interest (n) varies because of missing data or nonresponse. Percentages do not always sum to 100% because of rounding.

b Percentages of respondents answering “yes” (binary item, yes/no) when asked, respectively, “Do you use computer order entry when prescribing?” and “Do you use PDA when prescribing?”

c Percentage of respondents answering 4 (often) or 5 (always) when asked, “When writing prescriptions, how often do you use the following resources for information about prescription drugs?”

d Represents the percentage of respondents who did not use any information technology. Defined as responses of “no” for use of PDA and use of computer order entry, and Likert scale response of “never,” “rarely,” or “sometimes” for use of Internet services.

PDA = personal digital assistant.

price for the medication (25.8%), the preferred medications on the insurer’s formulary (11.9%), the patient’s pharmacy benefit structure (9.9%), or the required prescription copayments (12.2%). When asked how often they used various technologies when prescribing, 29.3% of respondents reported using a handheld device or PDA, 22.4% reported using the Internet, and 35.9% reported using handbooks or printed materials often or always (Table 3). When asked in binary fashion (yes/no) whether they use a PDA or computer order entry when prescribing, 33.9% of respondents reported using a PDA and 39.3% reported using computer order entry (Table 2). Internal consistency (reliability) among all Likert scale-type responses was considered good (Cronbach’s alpha = 0.82).

The mean number of prescriptions written per day among surveyed physicians was 22 (SD 17.8, data not shown). According to the survey, 89% of physicians reported being contacted in a typical day of practice to change a prescription from a nonformulary or nonpreferred drug to a formulary or preferred drug. Furthermore, physicians reported receiving, on average, 2.7 contacts per day (an estimated 12.2% of daily prescriptions) from a pharmacist or patient to change the prescription from a nonpreferred to a preferred drug. Two-thirds of physicians reported that prescriptions were changed to the preferred drugs in these instances. Only 16.7% of the physicians (n = 48) provided comments about formulary compliance. Reported challenges included time spent by physicians taking calls from patients or pharmacists (n = 5), lack of reimbursement for this time spent (n = 4), difficulty in retrieving up-to-date formulary information (n = 11), lack of formulary information (n = 16), and formulary organization not by diagnosis (n = 1).

Physicians’ Opinions About Prescribing, Demographics, and Information Technology Use

Table 4 contains descriptive information for key outcome variables (opinions about responsibility to minimize patient out-of-pocket cost and total cost, awareness of formulary medications, and perceived responsibility to prescribe formulary medications) and predictor variables, including demographics and use of information technology. Female physicians were more often aware (17.4%) of the preferred medication on a patient’s insurer’s formulary than were male physicians (9.3%, P = 0.048). Physicians not using a PDA when prescribing were more likely to agree that it was important to prescribe the drug with the lowest total cost than were physicians who used a PDA (85.5% vs. 74.5%, P = 0.023). With that exception, use of information technology, including PDA, Internet, and computer order entry, was not significantly related to any of the key outcome measures. The percentages of physicians reporting awareness of the medications on a patient’s formulary were 13.3% and 11.6% for those who answered “yes” when asked whether they use a PDA or computer order entry, respectively; 13.6% for those who reported using the Internet often or always; and 13.6% for those not using any information technology (comparison of those using ≥1 vs. 0 technologies P = 0.477). Physician specialty (generalist vs. specialist) also was not related significantly to any of the key outcome measures.

Physician Specialty

Statistically significant differences between physician specialty and other variables are reported in Table 5. Generalists were...
more often aware of the patient’s insurer than were specialists (41.1% vs. 19.2%, P < 0.001), more often used a PDA when writing a prescription (38.9% vs. 21.1%, P = 0.005) and more frequently reported being introduced to cost-effective prescribing during residency training (49.8% vs. 33.8%, P = 0.018). Conversely, when writing prescriptions specialists were more likely than generalists to report using the Internet or handbooks often or always (Internet: 33.3% vs. 18.1%, respectively, P = 0.006; handbooks: 45.6% vs. 32.2%, respectively, P = 0.035).

Of the comparisons between Minnesota physicians versus North Dakota physicians on key outcome variables, only 1 was statistically significant. Use of computerized order entry at the time of prescribing was more common in Minnesota (47.3%) than in North Dakota (28.3%, P = 0.001).

**Discussion**

Our findings have implications for patients, physicians, and health plans. A vast majority of the physicians in this study believed that it was important to prescribe the drug that would lower total costs as well as patients' copayments. However, only a minority of physicians believed that it was their responsibility to prescribe preferred medications.

Physicians’ opinions about prescribing and drug costs as reported in our study were similar to results of previous studies conducted with physicians in California.2–4 However, compared with the California studies, a higher percentage of physicians in our study were generally unaware of determinants of a patient’s prescription copayments. This lack of awareness might make prescribing in 3-tier formulary environments even more challenging.2–4 In our study, 35% and 12% of physicians reported being often or always aware of a patient’s insurer and preferred formulary options, respectively. In the California study, 53% and 33% of physicians reported being familiar most or all of the time with the patient’s insurer and preferred formulary options, respectively.3 Several factors could contribute to this finding. First, physicians in our study prescribed from more formularies.
TABLE 4  Key Opinion Measures by Demographic Characteristics and Use of Information Technologies<sup>a</sup>

<table>
<thead>
<tr>
<th>Age Group (Years)</th>
<th>When choosing among equally effective and safe medications, it is important for me to prescribe the drug that will minimize my patient’s out-of-pocket costs&lt;sup&gt;b&lt;/sup&gt; % (n)</th>
<th>When choosing among equally effective and safe medications, it is important for me to prescribe the drug that has the lowest total costs&lt;sup&gt;b&lt;/sup&gt; % (n)</th>
<th>I am personally aware of the “preferred” medications on the patient’s insurer’s formulary&lt;sup&gt;c&lt;/sup&gt; % (n)</th>
<th>It is my responsibility to prescribe “preferred” formulary medications&lt;sup&gt;b&lt;/sup&gt; % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Younger than 35</td>
<td>89.7% (26)</td>
<td>93.1% (27)</td>
<td>10.3% (3)</td>
<td>37.9% (11)</td>
</tr>
<tr>
<td>35-50</td>
<td>94.1% (128)</td>
<td>77.9% (106)</td>
<td>12.4% (17)</td>
<td>26.7% (36)</td>
</tr>
<tr>
<td>Older than 50</td>
<td>93.0% (107)</td>
<td>81.6% (93)</td>
<td>12.2% (14)</td>
<td>38.9% (44)</td>
</tr>
<tr>
<td>P values</td>
<td>0.683</td>
<td>0.164</td>
<td>0.953</td>
<td>0.101</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>93.8% (182)</td>
<td>81.9% (158)</td>
<td>9.3% (18)</td>
<td>30.5% (38)</td>
</tr>
<tr>
<td>Female</td>
<td>92.3% (84)</td>
<td>80.2% (73)</td>
<td>17.4% (16)</td>
<td>37.4% (34)</td>
</tr>
<tr>
<td>P values</td>
<td>0.635</td>
<td>0.740</td>
<td>0.048</td>
<td>0.253</td>
</tr>
<tr>
<td>Physician Specialty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generalist</td>
<td>94.0% (202)</td>
<td>83.2% (178)</td>
<td>12.6% (27)</td>
<td>35.9% (76)</td>
</tr>
<tr>
<td>Specialist</td>
<td>92.0% (69)</td>
<td>77.3% (58)</td>
<td>10.3% (8)</td>
<td>25.7% (19)</td>
</tr>
<tr>
<td>P values</td>
<td>0.556</td>
<td>0.260</td>
<td>0.583</td>
<td>0.110</td>
</tr>
<tr>
<td>Use of Technology When Prescribing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uses PDA&lt;sup&gt;d&lt;/sup&gt;</td>
<td>90.8% (89)</td>
<td>74.5% (73)</td>
<td>13.3% (13)</td>
<td>29.9% (29)</td>
</tr>
<tr>
<td>Does not use PDA&lt;sup&gt;d&lt;/sup&gt;</td>
<td>94.6% (177)</td>
<td>85.5% (159)</td>
<td>11.1% (21)</td>
<td>34.8% (64)</td>
</tr>
<tr>
<td>P values</td>
<td>0.218</td>
<td>0.023</td>
<td>0.592</td>
<td>0.408</td>
</tr>
<tr>
<td>Uses Internet&lt;sup&gt;e&lt;/sup&gt;</td>
<td>90.6% (58)</td>
<td>78.1% (50)</td>
<td>13.6% (9)</td>
<td>28.1% (18)</td>
</tr>
<tr>
<td>Does not use Internet&lt;sup&gt;e&lt;/sup&gt;</td>
<td>94.3% (214)</td>
<td>82.7% (187)</td>
<td>11.5% (26)</td>
<td>35.0% (78)</td>
</tr>
<tr>
<td>P values</td>
<td>0.297</td>
<td>0.399</td>
<td>0.630</td>
<td>0.306</td>
</tr>
<tr>
<td>Uses computer order entry&lt;sup&gt;f&lt;/sup&gt;</td>
<td>93.7% (104)</td>
<td>82.9% (92)</td>
<td>11.6% (13)</td>
<td>27.5% (30)</td>
</tr>
<tr>
<td>Does not use computer order entry&lt;sup&gt;f&lt;/sup&gt;</td>
<td>93.1% (163)</td>
<td>82.2% (143)</td>
<td>11.4% (20)</td>
<td>37.0% (64)</td>
</tr>
<tr>
<td>P values</td>
<td>0.855</td>
<td>0.880</td>
<td>0.950</td>
<td>0.100</td>
</tr>
<tr>
<td>Uses at least 1 information technology&lt;sup&gt;g&lt;/sup&gt;</td>
<td>93.3% (182)</td>
<td>80.5% (157)</td>
<td>10.7% (21)</td>
<td>30.6% (59)</td>
</tr>
<tr>
<td>Does not use any information technology&lt;sup&gt;g&lt;/sup&gt;</td>
<td>93.1% (81)</td>
<td>86.1% (74)</td>
<td>13.6% (12)</td>
<td>40.0% (34)</td>
</tr>
<tr>
<td>P values</td>
<td>0.943</td>
<td>0.264</td>
<td>0.477</td>
<td>0.125</td>
</tr>
</tbody>
</table>

<sup>a</sup>Statistical significance assessed using Pearson chi-square test. P values represent comparisons between groups shown in rows. Number of responses to the item of interest (n) varies because of missing data or nonresponse.

<sup>b</sup>The response scale for these items ranged from strongly disagree (1) to strongly agree (5). Agreement is defined as a rating of 4 or 5.

<sup>c</sup>The response scale for this item ranged from never (1) to always (5). A positive answer is defined as a rating of 4 or 5.

<sup>d</sup>Respondents answering “yes” or “no” (binary item, yes/no) when asked “Do you use PDA when prescribing?”

<sup>e</sup>The response scale for this item ranged from never (1) to always (5). A positive answer (i.e., uses Internet) is defined as a rating of 4 or 5.

<sup>f</sup>Respondents answering “yes” or “no” (binary item, yes/no) when asked “Do you use computer order entry when prescribing?”

<sup>g</sup>“Uses at least 1 information technology” was defined as a response of “yes” for use of PDA or use of computer order entry or Likert scale response of often (4) or always (5) for use of Internet services. “Does not use any information technology” was defined as responses of “no” for use of PDA and computer order entry, and Likert scale response of “never,” “rarely,” or “sometimes” for use of Internet services.

PDA = personal digital assistant.
TABLE 5  
Physician Specialty and Awareness of Pharmacy Benefit Plan and Use of Prescription Drug Information

|                          | Generalist % (n) | Specialist % (n) | P Value
|--------------------------|-----------------|-----------------|----------------
| The identity or name of your patient’s insurer | 41.1% (88)       | 19.2% (13)       | 0.001          |
| The “preferred” medications on your patient’s insurer’s formulary | 12.6% (27)       | 10.3% (8)        | 0.583          |
| Being introduced to cost-effective prescribing in residency training | 49.8% (103)      | 33.8% (25)       | 0.018          |
| Used the Internet when writing a prescription | 18.1% (39)       | 33.3% (26)       | 0.006          |
| Used handbooks when writing a prescription | 32.2% (69)       | 45.6% (36)       | 0.035          |
| Used a PDA when writing a prescription | 38.9% (82)       | 21.1% (16)       | 0.005          |

a Number of responses to item of interest (n) varies because of missing data or lack of response.

b Statistical significance assessed using Pearson chi-square test.

c Percentage of respondents answering 4 (often) or 5 (always) when asked “When writing prescriptions, how often do you use the following resources for information about prescription drugs?”

d Percentage of respondents answering “yes” (binary item, yes/no) when asked “Do you use PDA when prescribing?”

PDA = personal digital assistant.

Only 12% of physicians in the present study reported prescribing from 0 to 1 formularies, 19% reported prescribing from 2 to 5 formularies, and 26% reported prescribing from 6 or more formularies (Figure 3).1 In California, where staff-model HMOs comprise a substantial market share, a larger percentage of physicians (40%) reported prescribing from 0 to 1 formularies; 14% of the California study physicians reported prescribing from 2 to 5 formularies, and 19% reported prescribing from 6 or more formularies.3 Second, it is possible that variables not measured in previous research2,4 or in the present study (e.g., frequency of insurance provider changes or formulary updates) may have influenced awareness of patients’ insurers and preferred formulary options.

Our survey data are consistent with Shrank et al.’s data in several respects.2,3 Specifically, in the present study, generalists were more aware of a patient’s formulary than were specialists. Shrank et al. reported that generalists were twice as likely as specialists to report familiarity with patients’ formularies.2 Similarly, we found that generalists were more likely than specialists to report that they were aware of the identity of the patient’s insurer. Additionally, 60%-70% of physicians in both surveys reported that they never or rarely are aware of a patient’s required prescription copayment despite a majority (91% in Shrank et al., 94% in the present study) agreeing that it was important to prescribe drugs that would minimize copayments. It appears that more effective strategies to close the gap between prescribers’ stated desire to minimize patient copayments and the ability do so are needed.

Prescribing from multiple formularies will likely make it more challenging for physicians to be aware of patient prescription copayments because of differences among drug plans. Our findings support the premise that physicians practicing in different parts of the country face a variety of challenges while prescribing in a multi-tier formulary environment. Consequently, a larger, more representative nationwide study to determine the challenges physicians may face when prescribing in environments with multi-tiered drug benefit plans would be useful.

Eighty-nine percent of the physicians reported being contacted in a typical day of practice to change a prescription from a nonformulary or nonpreferred drug to a formulary or preferred drug. Pharmacists play a key role in lowering prescription copayments for patients with multi-tier copayment plans.2,3,26-28 However, a pharmacist’s role in this process needs to be reevaluated in terms of the nationwide pharmacist shortage, which is more severe in rural areas.29-32 Paying pharmacists for time spent calling physicians to request a change in prescription to a more cost-effective drug has been proposed. Whether this strategy significantly increases the use of more cost-effective medication requires further study.33,34

Limitations

Our study has several limitations. First, this study reflects the perceptions of members of the Minnesota Medical Association and the North Dakota Medical Association, who may not represent physicians who practice elsewhere. Second, we do not know the opinions of about half of the recipients of the survey who did not respond, and we have no information about these nonrespondents. However, we note that a study conducted by Shrank et al.3 using a similar survey instrument had a nearly identical response rate (49.6%), and a telephone follow-up of nonresponders determined that the nonresponders and responders were similar.

Third, as with any survey, our findings may be subject to a nonresponse and social desirability response bias. In particular, the wording of both the survey introduction (“challenges you may be facing with Medicare Part D”) and the heading of the survey section that was the source of most of the items reported here (“prescribing challenges”) may have encouraged responses from physicians experiencing prescribing difficulties, especially with Medicare Part D.
**Conclusion**

Although surveyed physicians believed that it was important to prescribe drugs that would minimize patients' prescription copayments and total drug costs, they were often unaware of the details needed to enable them to do so. Making this information more available to physicians has the potential to increase prescribing of medications with lower copayments and to increase patient access to needed medications.

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Shamima Khan was primarily responsible for study concept and design, data collection, and data interpretation with assistance from David Scott and Bruce Pitts. All 4 authors contributed equally to writing and revision of the manuscript.

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**REFERENCES**

Physicians’ Opinions About Responsibility for Patient Out-of-Pocket Costs and Formulary Prescribing in Two Midwestern States


27. Personal communication with Lisa Johnson, Staff Pharmacist, MeritCare Mills Avenue Pharmacy, Fargo, North Dakota. May 21, 2007.

28. Personal communication with Ross Wilhelm, Assistant Professor, Department of Pharmacy Practice, North Dakota State University, Fargo, North Dakota. May 23, 2007.


CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII), more commonly known as insulin pump therapy, was first established in the marketplace in the 1980s and is now one of 3 currently available modalities for the delivery of insulin in managing diabetes. Other modalities for insulin delivery include syringe-injected and pen-injected. In the United States in 2007, an estimated 569,000 patients, representing about 12% of patients taking insulin, used CSII for insulin administration; 75% used syringes and 22% used pens. CSII users currently represent about 3% of the 17.9 million patients diagnosed with diabetes in the United States.

WHAT IS INSULIN PUMP THERAPY?

Of all the insulin delivery modalities, CSII is the route that with optimal utilization most closely mimics the physiological actions of the pancreas. The external device consists of a small battery-operated electromechanical pump that is programmed to deliver insulin stored in a small reservoir. Insulin is delivered by the pump in 2 ways: (a) as basal insulin, or insulin that is delivered at programmed rates throughout the entire day to match the individual’s baseline insulin requirements, or (b) as a bolus that provides an additional boost of insulin to cover for ingested carbohydrates or elevated blood glucose levels. The amount of the insulin bolus is calculated using the pump and is managed by the patient. Rapid-acting insulin, including lispro, aspart, and glulisine, is the recommended insulin for pump therapy because of improved absorption profiles. Amounts of insulin as small as 0.025 units are delivered into the subcutaneous tissue from the pump through small tubing called a cannula. The insulin is then absorbed from the subcutaneous tissue at similar rates as when injected by syringe or pen.

Bolus insulin is provided by the pump in an on-demand fashion based on carbohydrate intake or varying degrees of hyperglycemia experienced by the patient. To calculate the amount of insulin to be delivered for carbohydrate intake, a commonly used method is to divide 500 by the patient’s previous total daily dose (TDD) of insulin; for example, in a patient using 50 units (U) per mL per day, the insulin-to-carbohydrate coverage ratio is 1 U to cover 10 grams of carbohydrates. For a bolus related to hyperglycemia, the pump uses a programmed insulin sensitivity factor, also known as a correction factor, to calculate the appropriate amount of insulin to lower the blood glucose level to an established target range. To calculate the correction factor, a commonly used approach for rapid-acting insulin is to divide 1,800 by the TDD, although various methods have been suggested. In addition, initial basal and bolus rates are calculated based on the patient’s pre-pump insulin usage requirements and are titrated according to the individual’s response.

ADVANTAGES AND DISADVANTAGES OF INSULIN PUMP THERAPY

Current evidence for CSII in type 1 diabetes is well established. Most studies suggest that, compared with administration of insulin via multiple daily injections, CSII provides equivalent or better glycemic control using less insulin, with fewer and less severe hypoglycemic events. Pickup et al.’s 2002 meta-analysis of 12 randomized controlled trials comparing CSII with multiple daily injections showed that CSII significantly improved glycemic control while reducing the required daily insulin dose by 14%. In a 2004 meta-analysis, Retnakaran et al. concluded that among patients with type 1 diabetes treated with rapid-acting insulin analogs, CSII produced better glycemic control than did multiple daily injections; the improvement in hemoglobin A1c that was associated with CSII use was greater for patients with higher A1c at baseline. Pickup et al. (2006) found that among patients with type 1 diabetes, those with poor diabetes control under multiple daily injections benefited from a switch to CSII to a greater degree than did patients who were well controlled with injection-administered insulin.

The evidence for CSII in type 2 diabetes remains limited. In Raskin et al.’s study of patients with type 2 diabetes, CSII and multiple daily injections were found to be equally efficacious and safe, but 93% of CSII users expressed a preference for CSII compared with their previous regimen of multiple daily injections. Herman et al. compared CSII with multiple daily injections in a sample of patients aged 60 or older with type 2 diabetes; efficacy, rates of hypoglycemia, and weight gain were similar in the 2 treatment modalities. A study by Wainstein et al. focused on CSII in a sample of obese patients with type 2 diabetes and found improvement in A1c over multiple daily injections without significant changes in weight, although goal A1c levels were not attained. These studies suggest that CSII should be considered for type 2 diabetes patients requiring intensive insulin therapy, but more studies are needed.

One clear advantage that pump therapy provides is the decreased number of syringe needle sticks that are required. Once the cannula is inserted under the skin, it may be worn
in the same position for up to 72 hours. It is estimated that compared with multiple daily injections, which can require 4 or more injections a day, the number of annual syringe needle sticks decreases from approximately 1,460 to 156 when using an insulin pump. CSII also provides greater flexibility; for example, basal rates can be adjusted to correct for “dawn phenomenon,” a period of high blood glucose in the morning.

Disadvantages also exist for pump therapy. Cost remains a large obstacle for many patients, with the initial cost of an insulin pump and supplies ranging between $4,995 and $6,500.3,17,18 Because the insulin pump delivers only very small subcutaneous amounts of insulin analogues with a short activity life, there is an increased risk for developing diabetic ketoacidosis (DKA) if insulin delivery is interrupted. Because of this risk, it is important that patients self-monitor blood glucose frequently throughout the day.3,4,18 Thus, patients using insulin pumps may require as many finger sticks as patients using multiple daily insulin injections.3 Fortunately, it has been shown that the rate of DKA with pumps has been reduced with proper pump education and management.1,4 The most common complications of pump therapy are infusion site irritation, occlusion, or, occasionally, infection.9

Finally, CSII is a complex mode of insulin delivery when considering patient ease of use.3 Patients under consideration as candidates for CSII should be evaluated closely to determine if they are capable and motivated to learn CSII techniques, which include carbohydrate counting and frequent self-monitoring (Table 1).19 CSII is discouraged for patients who have a history of noncompliance with self-monitoring or current insulin regimens, significant psychological problems, or learning disabilities.1,4,19 A review of 25 years of CSII provided a framework for considering pump therapy, concluding that “special expertise and adequate educational facilities are needed by the medical team to initiate and supervise pump patients.”21 Proper training of the patient is necessary to minimize the effect of the complexity of CSII in day-to-day care.

Community Pharmacists and the Insulin Pump Market

Although CSII was once primarily a tool utilized by endocrinologists and other diabetes specialists, it is reasonable to assume that more nonspecialty practitioners will be incorporating CSII into their practices, given the prevalence of diabetes in the United States—a record 23.6 million people, counting both diagnosed and undiagnosed cases, and an estimated 57 million individuals with pre-diabetes.3 The potential for growth in the use of CSII by nonspecialists creates an environment and opportunity for pharmacists to work with them in the management of CSII.

Traditionally, training of pump patients is performed primarily by case managers employed by the pump manufacturer or by certified consultant pump trainers, such as registered nurses certified as diabetes educators. Pharmacists currently play a role in training patients in the proper use and administration of all insulin delivery modalities but are rarely involved in CSII training. Although the current count of pharmacists acting as CSII trainers is unknown, in 2003 the editor of a newsletter for medical professionals involved in diabetes care estimated that fewer than 20 pharmacists in the United States were certified to provide CSII education.20 Growth in the market for CSII trainers creates an environment in which pharmacists can fill a need for high-quality education, training, and management for CSII.

In its position statement on CSII, the American Diabetes Association (ADA) indicates that CSII should be “prescribed, implemented, and followed by a skilled professional team familiar with CSII therapy and capable of supporting the patient.”21 Under the right conditions, the community pharmacy can operate as a convenient center of CSII support and information for the population of patients with diabetes that it serves. Community pharmacies are already established as a point of access for the dispensing of diabetes medications, including insulin and testing supplies such as strips, lancets, and glucose monitors. Enabling the pharmacist to act as an educator can improve the coordination of care and the efficient use of these medical tools. Many pharmacies also are providers of durable medical equipment, a role that positions them as a logical point of sale for the pump and monthly supplies.

The Causey Pharmacy Model for Insulin Pump Training and Management

Causey's Pharmacy is an independent community pharmacy that has been providing CSII training and management, using a systematic approach to CSII therapy initiation, since 2002. The pharmacy program is ADA recognized, and several of the pharmacists are Certified Diabetes Educators (CDEs). The goal of the pharmacist is to complete initial training and management in 2 months, but it may take up to 6 months in some complicated cases.

Patients who are potential candidates for CSII are identified by 3 mechanisms: (a) referral from the insulin pump manufacturer, (b)
referral from the treating physician, and (c) patient identification by the pharmacist educator during routine self-management training. Once a patient is identified as a potential CSII candidate, the pharmacist educator evaluates the patient's appropriateness for CSII. If the patient is considered an appropriate candidate, the patient and the family or support structure are invited to a session that introduces CSII. During this session, the advantages and disadvantages of CSII are discussed, followed by a demonstration of the insulin pump and infusion sets. At this point, if the individual accepts CSII, cost issues are evaluated and insurance paperwork is completed.

Once the patient has been approved for CSII by the insurance company, training is initiated. Pre-pump training is typically divided into 2 sessions, “Carb Counting” and “Button Pushing,” but can be amended to meet the individual patient’s needs and learning capacity. During “Carb Counting,” the pharmacist educator introduces or reviews appropriate carbohydrate counting technique. At a subsequent visit, the patient’s comprehension and skill are then assessed through a 3-day food diary reviewed by the pharmacist educator. Additionally, the pharmacist educator reviews self-management skills, such as treating hypoglycemia and hyperglycemia or maintaining glucose control during exercise and illness. During the second pre-pump session, referred to as “Button Pushing,” the pharmacist educator reviews the technology and mechanics of working the pump; the session includes topics such as navigating the pump menus, setting insulin infusion rates, loading the insulin cartridge and priming the tubing, and day-to-day handling and functioning of the pump.

During pre-pump training, the pharmacist educator also gathers relevant patient information to determine starting basal rates and bolus settings, establishes a collaborative relationship with the prescribing physician, and works to obtain signed orders for initiation and titration according to an established protocol. The protocol delineates (a) the change in the patient’s current insulin regimen within the first 24 hours prior to the pump start, such as how the basal insulin will be reduced prior to the pump start; and (b) how the pharmacist educator will make changes in the basal rates, the insulin-to-carbohydrate ratio, and the insulin sensitivity factor during the time period when the pharmacist manages the patient. The protocol also establishes a communication path through which the prescribing physician and pharmacist educator communicate during the management period.

During the “Button Pushing” training session, patients use normal saline to initially learn proper insulin cartridge loading and insulin pump priming. The patient may also be given the option of a saline trial session in which the pump is worn for a few days while normal saline is infused in place of insulin and the patient’s injection regimen is continued. This is especially useful for patients who are apprehensive about pump therapy or have difficulty mastering the pump. After all pre-pump training is completed, the next step is the actual pump start. Prior to the pump start, the pharmacist educator instructs the patient on how to discontinue or adjust the current insulin regimen. During the pump start visit, many important learning issues for CSII are reinforced for the patient. The patient then self-loads the cartridge with rapid-acting insulin and an infusion set is inserted. The pharmacist educator also provides appropriate monitoring and follow-up schedules for the patient. Typically the first follow-up phone call is within 12 hours of the pump start.

Following the initiation of the pump, the patient reports back to the pharmacist educator on a daily basis until blood glucose numbers are stable and any patterns of hypoglycemia or hyperglycemia are corrected. This initial stabilization period can range from a few days to 1 week. After this initial titration period, the patient continues to report back to the pharmacist educator on a weekly basis for approximately 1 to 2 months. A follow-up visit is scheduled between 1 and 3 weeks at which advanced techniques of pump therapy are introduced to the patient. These techniques include use of dual wave boluses (i.e., setting multiple basal patterns based on basal insulin requirements throughout the day), the use of temporary basal rates, and pattern management.

During the initial weeks of CSII training, patients are taught how to perform basal testing. Basal testing is a systematic method for determining if the basal rates are set appropriately. Blood glucose is measured every 2 to 3 hours for a defined period of time during which the patient does not eat or use supplemental (bolus) insulin. The pharmacist uses these readings to determine the appropriateness of the basal rate and make adjustments according to protocol as necessary. Once basal testing is completed, the insulin sensitivity factor and insulin-to-carbohydrate ratio are tested and adjusted if needed according to protocol.

### Sources of Reimbursement for Pharmacist Services

Multiple financial resources exist for the pharmacist who serves as a certified pump trainer. The pharmacist gains reimbursement directly through the pump company for the initial training and management at a fixed rate that covers up to 2 months of training and management. There is no patient financial responsibility for the training and management services for these 2 months. If any additional education or management is required by the patient after the 2 months of initial training, the pharmacist educator may bill the patient’s individual insurance provider under diabetes education and self-management codes (Healthcare Common Procedure Coding System codes G0108 and G0109) provided that the pharmacist practices in an ADA-recognized program. Most patients will have cost-sharing that the pharmacist must collect in the form of deductibles or copayments.
In addition to providing technical instruction to patients on the safe operation of insulin pumps, some pump trainers may also provide patient management and follow-up for a short period following training. These responsibilities should be discussed first with the prescribing physician. It is also important to note that pharmacist educators should perform responsibilities only within their scope of practice, which is governed by their respective professional licensing body. To aid in the management of patients, pharmacists may need to establish a collaborative practice agreement that delineates the role and responsibilities of the pharmacist as well as the titration protocol to be followed for insulin adjustments. Pharmacist educators should also be prepared to provide support to their patients after-hours, on holidays, and on weekends.

**Conclusion**

Because of the time commitment and complexities of CSII, practitioners may not feel comfortable prescribing it. This barrier can be overcome by collaborating with a pharmacist educator who is trained and knowledgeable regarding CSII, allowing the patient to receive more intense initial education and management. Successful implementation of CSII hinges on 2 main components—a motivated patient with developed self-management skills and a focused program conducted by knowledgeable practitioners who can provide education, management, and support.

**Qualifications and Time Commitment for Pharmacists Working as Insulin Pump Trainers**

A growing number of pharmacists are trained and work as CDEs. Currently there are over 15,506 CDEs in the United States, the vast majority (96%) of whom are nurses and dietitians. As of 2007, the National Certification Board of Diabetes Educators has certified 691 pharmacists (about 4% of CDEs nationwide) who have successfully passed their examination and met their practice requirements to obtain the CDE credential; it is unknown how many of these are currently acting as CSII trainers. Although certification as a CDE is not a requirement to become a certified pump trainer, it is highly recommended that pharmacists obtain their CDE if they are to provide CSII training and management. Additional instruction by the clinical staff of the insulin pump manufacturer is also helpful.

Current requirements for becoming a certified pump trainer, sometimes called a certified product trainer, are established by the insulin pump manufacturer. To be eligible for consideration, the individual must first possess a license in one of many health fields or hold a master’s degree in a designated area as listed in Table 2.23 The individual must study and understand the individual pump product as well as premises behind CSII and diabetes management, complete a hands-on training program, and demonstrate proficiency in training skills. Many companies also require the trainer to pass a written test with a minimum established score. The individual must also show proof of current professional liability insurance.

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REFERENCES


