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Medicare Part D—A Roundtable Discussion of Current Issues and Trends

Donald C. Balfour III, MD, FACP; Steven Evans, MD; Jeff Januska, PharmD;

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Supplement

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Supplements to the *Journal of Managed Care Pharmacy* are intended to support medical education and research in areas of clinical practice, health care quality improvement, or efficient administration and delivery of health benefits. The following standards are applied to all *JMCP* supplements to ensure quality and assist readers in evaluating potential bias and determining alternate explanations for findings and results.
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6. Seek and publish content that does not duplicate content in the *Journal of Managed Care Pharmacy*.
7. Subject all supplements to expert peer review.

FACULTY

Donald C. Balfour III, MD, FACP, is President and Medical Director of Sharp Rees-Stealy Medical Group (SRSMG), which includes more than 376 physicians representing over 30 medical specialties at 16 medical centers throughout San Diego County. The medical group provides comprehensive medical care to 145,000 HMO patients, including 15,000 seniors. His responsibilities include the management of physician, nurse practitioner, and physician assistant staff at all countywide locations, maintaining their employment agreements and negotiating contracts for services rendered by outside providers. He is also responsible for the review and negotiation of provider agreement contracts with all health plans. Dr. Balfour oversees the preparation and management of the group's operating budget and the negotiation of the annual compensation agreement with the Sharp Rees-Stealy Division (SRS). Dr. Balfour, in partnership with the Administrator of SRS, is responsible for clinic operations, physician and staff management, quality assurance compliance, and fiscal soundness of SRS.

Dr. Balfour was a past Associate Professor of Medicine, Department of Medicine, at the University of California School of Medicine in San Diego. He is a Fellow of the American College of Physicians and a past Governor of the College. Dr. Balfour was President of the American Medical Group Association and a founding Board member of the California Association of Healthcare Providers. He has been an Executive Committee member and a Governing Board member of the California Association of Physician Groups (CAPG) for the past 5 years.

Dr. Balfour has been President of the SRSMG Board of Directors since 1985 and currently serves as the President and Medical Director. He was instrumental in the development of a physician compensation methodology based on capitation in response to the expanding managed care market and the development and implementation of the Practice Assessment Report (PAR), a physician "profile" designed to measure quality indicators that link physician performance to compensation.

Dr. Balfour earned his medical degree from Northwestern University Medical School. He completed his residency in Internal Medicine and Hematology fellowship at Mayo Graduate School in Rochester, Minnesota. Dr. Balfour was a Major in the U. S. Air Force and served as Chief of the Outpatient Department at Hickman Air Force Base, Hawaii.

Steven Evans, MD, is Vice President of Medical Affairs and Pharmacy Director, Health Plan of Nevada, in Las Vegas. He is also Chairman of the plan's Pharmacy and Therapeutics Committee as well as Medical Director of the SMA Surgery Center and chairman of the plan's New Medical Technology Committee.

Prior to his position with Health Plan of Nevada, Dr. Evans held several positions at Southwest Medical Associates in Las Vegas, including Medical Director, Clinic Chief of Surgery, and Facility Director for Anesthesia, Gastroenterology and Urology. Dr. Evans also served on the Board of Directors during his tenure at Southwest Medical Associates and is on the Board of Trustees for the University of Southern Nevada.

Dr. Evans earned his bachelor of science degree in psychobiology from the University of Southern California and his medical degree from UCLA Medical School. He subsequently completed an internship in Internal Medicine at UCLA Medical Center, and a residency in Anesthesiology at the University of California, San Diego, Medical Center.

Jeff Januska, PharmD, is Director of Pharmacy Services for CenCal Health, a regional Medicaid managed care health plan serving members of Santa Barbara and San Luis Obispo counties in California. His current responsibilities include formulary management, quality and utilization management, pharmacy benefit design, and Chairman of the Pharmacy and Therapeutics Committee. Dr. Januska introduced a specialty pharmacy program at CenCal Health in 2006 and has since shared specialty outcomes successes in the areas of oncology and hepatitis C at several venues, including the California Department of Health Care Services Managed Care forums.

Prior to joining CenCal Health, Dr. Januska practiced in several settings for almost 20 years, including industry (Amgen), acute care, managed care (Kaiser), and academia (adjunct professor at the University of the Pacific in Stockton, California). His areas of teaching interest were adult critical care medicine, internal medicine, and infusion therapy. In the early 1990s, he managed a home infusion business on the island of Maui, Hawaii. He currently serves as a peer reviewer for *American Health & Drug Benefits*.

Dr. Januska earned his undergraduate degree in chemistry, pre-pharmacy, from the University of California, Irvine, and his doctorate of pharmacy degree from the University of Southern California.

Helen Y. Lee, PharmD, MBA, is a Clinical Pharmacist with CareFirst BlueCross BlueShield, a not-for-profit managed health care plan in Baltimore, Maryland, serving 3.1 million members in the Mid-Atlantic region including the Maryland, District of Columbia, and Northern Virginia areas. CareFirst has approximately one-half million members in the Federal Employees Health Benefits Program (FEHBP), 1.2 million commercial pharmacy members, and 36,000 Medicare PDP members. Her main roles and responsibilities include formulary management, contracting, drug utilization reviews, management of the Pharmacy and Therapeutics Committee, and serving as a preceptor

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Dr. Lee previously was Senior Clinical Pharmacist with Independence Blue Cross in Philadelphia, Pennsylvania. She has been a member of the Academy of Managed Care Pharmacy since 2001 and is a member of the National Association of Managed Care Physicians. She has contributed to several publications and was lead author of the article "Use of Secondary Prevention Drug Therapy in Patients With Acute Coronary Syndrome After Hospital Discharge," which was published in the April 2008 issue of *Journal of Managed Care Pharmacy*. She also contributed to the August 2008 *Journal of Managed Care Pharmacy* supplement "Current Issues and Trends in Medicare Part D." She was a panelist at "The Value of Pharmaceuticals: Coverage and Evidence Considerations" symposium on Capitol Hill in September 2007, presenting to congressional staff and academicians, researchers, and industry employees in the Baltimore-Washington, DC, area. She was a member of the Managed Care Women's Health Consensus Working Group that published "A Managed Care Consensus Statement on Contraception and Women's Health" in the May 2006 supplement of *Managed Care Interface*. She also coauthored "Utilization and Cost of Sildenafil in a Large Managed Care Organization With a Quantity Limit on Sildenafil" in the October 2005 issue of the *Journal of Managed Care Pharmacy*.

Dr. Lee earned her doctorate of pharmacy degree at the University of Maryland, Baltimore, and her master's of business administration degree from the University of Baltimore. She completed a managed care residency at the University of Maryland School of Pharmacy, which included working with Pfizer, Inc., and CareFirst BlueCross BlueShield.

Sonya J. Lewis, RPh, MBA, is Adjunct Professor of Pharmacy Practice at the University of Colorado School of Pharmacy in Denver, Colorado. As a Pharmacy Director with Blue Cross Blue Shield of Colorado/Nevada, she designed and launched the first 4-tier pharmacy benefit for commercial plans in the United States. This benefit design is now the industry standard.

A nationally recognized author, Ms. Lewis has published articles on 3-tier and 4-tier benefit design, patient attitudes towards their pharmacy benefit, and evidenced-based pharmacy practice, which have appeared in the *Journal of Managed Care Pharmacy, Drug Benefit Trends,* and *American Journal of Health-System Pharmacy*. Her most recent publication, "Biologics 101," is a web-based continuing education course for pharmacy directors, medical directors, and case managers who work with oncology and specialty medications. She is a committee member with the Academy of Managed Care Pharmacy, the Colorado Pharmacist Association, and Alpha Chi Sigma Professional Fraternity. Ms. Lewis is also a frequently invited speaker and is active with legislative and regulatory affairs in the Southwest region.

Ms. Lewis earned her bachelor of science degree in biology and a bachelor of science in pharmacy from the University of North Carolina at Chapel Hill. She earned her master's of business administration degree from the University of North Carolina at Greensboro and Strassford University.

Steve R. Nolan, PharmD, is the Pharmacy Director at Rocky Mountain Health Plans, a not-for-profit Colorado-based health plan serving over 177,000 commercial, Medicaid, Medicare, and self-funded members. Dr. Nolan is responsible for all operations of the pharmacy department including pharmacy and rebate contracting, PBM oversight, Pharmacy and Therapeutics Committee research and presentation, physician education activities, formulary development and maintenance, primary literature research and evaluation, regulatory compliance with Medicare Part D and Medicaid plans, drug utilization review, medication therapy management, and drug trend analysis and reporting.

Dr. Nolan has authored numerous articles on a variety of clinical topics in peer-reviewed publications, including *American Journal of Managed Care, Family Practice Management, Journal of Asthma, Journal of Critical Illness, Journal of the American Society of Consultant Pharmacists, US Pharmacist,* and *Southern Medical Journal*. He is a peer reviewer for a variety of publications including *Managed Care Interface, P&T Journal,* and *US Pharmacist*.

Dr. Nolan has been an invited speaker at many pharmacist and physician education programs, including the annual meetings of the American Thoracic Society and the American College of Apothecaries. Dr. Nolan is currently a member of the Academy of Managed Care Pharmacy, American Pharmaceutical Association, and American Society of Health-System Pharmacists, among others.

Dr. Nolan earned his bachelor of science degree in chemistry from

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Mark Noga, PharmD, RPh, CGP, is Regional Vice President, Clinical Pharmacy for Medicare at Coventry Health Care in Harrisburg, Pennsylvania. His current responsibilities include formulary management; Medicare program education and guidance to physicians, pharmacists, nurses, and internal business executives; analysis of the Medicare drug program; and evaluation of member drug use to develop and implement appropriate utilization management. In addition, Dr. Noga acts as a liaison to pharmaceutical manufacturers, contracted pharmacies, and the Center for Medicare and Medicaid Services. He serves on Coventry's national Medicare Pharmacy and Therapeutics Committee, as well as the national Commercial Pharmacy and Therapeutics Committee.

Prior to Coventry, Dr. Noga was employed at Pharmerica as a consultant pharmacist for long-term care. Dr. Noga has published numerous articles on the Medicare Part D prescription drug benefit for continuing pharmacy education. He is an active member in the Academy of Managed Care Pharmacy.

Dr. Noga earned his bachelor of science degree in pharmacy from the Philadelphia College of Pharmacy and Science in Philadelphia, Pennsylvania, and his doctorate of pharmacy degree from Shenandoah University in Winchester, Virginia. He obtained his CGP designation from the Commission for Certification in Geriatric Pharmacy.

Charles Stemple, DO, MBA, is Regional Medical Director for Humana Inc., a mixed health plan with approximately 3.2 million commercial members and 1 million Medicare Advantage-Prescription Drug Plan members. As Regional Medical Director, Dr. Stemple is responsible for all aspects of quality improvement, disease management, concurrent review, and case management for Humana's Midwest region with oversight of Ohio, Kentucky, Tennessee, and Indiana. Dr. Stemple is also National Medical Director for transplant and bariatric services, co-Chairman of Humana's technology assessment committee, and the clinical leader of all Humana renal disease initiatives and disease management programs for end-stage renal disease.

Dr. Stemple is a member of American College of Emergency Physicians, American Osteopathic Association, American College of Physician Executives, and Medical Society of Ohio.

Dr. Stemple earned his bachelor of science degree in social sciences (anthropology) from Ohio State University and his doctor of osteopathy degree from West Virginia School of Osteopathic Medicine. He also earned his master's of business administration degree from Xavier University. Dr. Stemple served a rotating internship at Brentwood Hospital in Ohio and his residency in Emergency Medicine at Akron General Medicine Center.

Kishan "Kit" Thapar, MD, MBBS, is Executive Director and Chief Executive Officer/Chief Medical Officer of ProMed Health Network, an IPA in Southern California with more than 110,000 members. His current responsibilities include contracting for health plans and providers and supervising the plan's Hospitalist Program, as well as its case managers. Additionally, Dr. Thapar serves as a member of the Quality, Utilization, and Credentialing Committees.

Prior to joining ProMed, Dr. Thapar was Chief Medical Officer of Primecare Medical Network, one of the premier provider networks in Southern California comprising 11 IPAs and a fully integrated staff model with its own hospital, with about 400,000 HMO patients.

Dr. Thapar is a member of the American College of Physicians and the California Medical Association. He also serves on the Pharmacy and Therapeutics Committee of Inter Valley Health Plan. Over the past 15 years, Dr. Thapar has given many talks regionally and nationally to his peers and other healthcare professionals. He was a member of Vascular Biology Group, a national organization, and completed a special rotation in Lipid Clinic at the University of California, Irvine/Veterans Administration, Long Beach Hospital. Dr. Thapar has worked extensively in the development of utilization and quality management policies and procedures and has collaborated with his colleagues to develop care guidelines in many areas of internal medicine.

Dr. Thapar earned his medical degree from Bombay University, India, and served his residency in Internal Medicine at the University of California, Irvine/Long Beach Veterans Administration Hospital.

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Learning Objectives

After reading these articles, participants should be able to do the following:

1. Review the key issues and challenges faced by payers in the current management and administration of the Part D benefit.

2. Discuss the current and future state of health information technology (i.e., e-prescribing and electronic health records) and their impact on the healthcare marketplace.

3. Evaluate important issues that have the potential to affect the future of Medicare Part D, including the financial stability of the Medicare program, the ongoing evolution of Part D plans, the increasing burden of the doughnut hole, and the potential for increased government involvement in drug pricing.

Note: This supplement does not offer continuing education credits for pharmacists or continuing medical education credits for physicians.

Disclosures

This supplement is based on a summit meeting in Seattle, Washington, on July 28, 2008, which was held to discuss issues that could potentially change how payers administer and manage their Part D benefits. Based on feedback received during the first Part D summit, this meeting specifically focused on health information technology and the overall management of Part D from a real-world perspective. During the roundtable discussion, the authors collectively discussed and developed the detailed outline for this *JMCP* supplement.

This meeting was sponsored by Takeda Pharmaceuticals North America, Inc., as part of its ongoing initiative, The Managed Care Leaders Program, which is designed to focus on key issues and trends that affect payers. The authors served as consultants to the sponsor and received compensation for participation and travel. Other than receipt of compensation for participation and travel, the authors disclose no potential bias or conflict of interest related to the subject of this supplement. Steve R. Nolan is an advisory board member for Takeda Pharmaceuticals North America, Inc. Kishan Thapar is a member of the speakers' bureau and receives speaking fees from Takeda Pharmaceuticals North America, Inc.

Medical writers Charlotte A. Kenreigh, Linda Timm Wagner, and Dennis Bloshuk, Editor, Strategic Healthcare Alliance, contributed the literature search to this supplement, as well as the writing and revision of the manuscripts.

Off-Label Use

The authors note that this supplement does not contain reference to any use of prescription drugs that is not approved by the U.S. Food and Drug Administration.

Disclaimer

The articles in this supplement represent the opinions of the authors and do not reflect the official policy or views of the Academy of Managed Care Pharmacy, the authors' institutions, or Takeda Pharmaceuticals North America, Inc., unless specified.

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ABSTRACT

BACKGROUND: Medicare Part D was introduced with a goal of provid-
ing access to prescription drug coverage for all Medicare beneficiaries.
Regulatory mandates and the changing landscape of health care require
continued evaluation of the state of the Part D benefit.

OBJECTIVE: To review the current state of plan offerings and highlight key
issues regarding the administration of the Part D benefit.

SUMMARY: The Part D drug benefit continues to evolve. The benefit value
appears to be diluted compared to the benefit value of large employer
plans. Regulatory restrictions mandated by the Centers for Medicare and
Medicaid Services (CMS) are reported to inhibit the ability of plans to
create an effective, competitive drug benefit for Medicare beneficiaries.
Management in this restrictive environment impedes competitive price
negotiations and formulary coverage issues continue to create confusion
especially for patients with chronic diseases. The doughnut hole cover-
age gap represents a significant cost-shifting issue for beneficiaries that
may impact medication adherence and persistence. To address these and
other challenges, CMS is working to improve the quality of care for Part D
beneficiaries by designing and supporting demonstration projects. Although
these projects are in different stages, all stakeholders are hopeful that they
will lead to the development of best practices by plans to help manage their
beneficiaries more efficiently.

CONCLUSIONS: A significant number of Medicare beneficiaries are current-
ly receiving prescription drug benefits through Part D. The true value of this
benefit has been called into question as a result of plan design parameters
that lead to cost-shifting, an increasing burden for enrollees. Concerns
regarding the ability to provide a competitive plan given the stringent rules
and regulations have been voiced by plan administrators. In an effort to
drive toward evidence-based solutions, CMS is working to improve the
overall quality of care through numerous demonstration projects.

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The Medicare Part D drug benefit was launched in January
2006 and marked an important change in the landscape
of Medicare. For the first time, Medicare recipients had
access to an outpatient prescription drug benefit. The challenges
and opportunities presented by the implementation of the Part D
program have been the focus of much discussion in and outside
of the medical community.

In December 2007, Takeda Pharmaceuticals North America,
Inc., sponsored a Part D Summit that was attended by medical
directors and pharmacy directors involved in the implementa-
tion of Part D programs at the plan level. The proceedings of the
meeting were reviewed and served as the basis of the August
2008 supplement issue of the *Journal of Managed Care Pharmacy*.
The supplement offered perspectives on key issues for managed
care organizations (MCOs) as they relate to Part D. During the
summer of 2008, a second Summit meeting was held to further
address issues that would impact payers in the management and
administration of the Part D beneficiary population. The 2008
Summit was attended by pharmacy directors and medical direc-
tors in managed care leadership positions. Key issues for the
2008 Summit—current and future administrative parameters
for providing health care benefits through Medicare Part D and
health information technology (HIT) integration with emphasis
on e-prescribing and electronic health records (EHR) in the
United States—were identified by participants during a previ-
ous Summit in 2007. During their discussions, the participants
guided the development of an outline and the content, which
served as the basis for this supplement.

■ Key Points From the 2007 Summit
The Evolution Is Continuous

Since Part D was first introduced, the number of enrollees has
increased, and many of the program offerings have changed.[1]
Plans have also altered the payment structure, shifting away from
deductibles and coinsurance to tiered copayments and coinsur-
ance with an increasing reliance on generic medications to hold
down costs.

The Emphasis on Management of Chronic Conditions Continues

Medication therapy management (MTM) programs are being
regulated by the Centers for Medicare and Medicaid Services
(CMS) to promote the safe and effective use of medications for
qualified beneficiaries.[2] However, current criteria to define mem-
bers who would benefit from MTM services only captures a small
proportion of all enrolled beneficiaries. In addition to expanding
these services to a larger number of patients, there is a need to

develop measures to assess the effectiveness of these programs. Special needs plans (SNPs), which are offered through Medicare Advantage, target the health needs of dual eligibles, institutionalized beneficiaries, and beneficiaries with certain chronic or disabling conditions (i.e., cardiovascular disease, diabetes, congestive heart failure, osteoarthritis, mental disorders, end-stage renal disease, and human immunodeficiency virus).[3] The coordination of care for these target populations has the potential to reduce hospitalizations and institutionalizations and improve medication use by reducing polypharmacy.

Quality Remains a Focus

The traditional fee-for-service (FFS) payment system used in Medicare created an environment that reimbursed health care providers for care regardless of the quality of that care.[4] In essence, incentives were somewhat misaligned, and there were no financial incentives to push for higher quality of care. In an effort to ensure the efficient use of Medicare resources, CMS has attempted to adopt strategies that promote improved quality of care for beneficiaries, such as Medicare Advantage, prospective payment, demonstration projects, and pay-for-performance (P4P).

Adoption of HIT Is Essential

CMS continues to evaluate the integration of HIT in an effort to streamline care and improve the quality and efficiency of health care delivery.[5] Although HIT offers the promise of improvement, the costs of implementing technologies such as EHR and e-prescribing contribute to a low rate of adoption. Through demonstration projects, it appears that CMS is attempting to provide data that will encourage support for financial investment in new technologies.[5]

Oversight May Impede Progress

Part D programs are subject to continued CMS oversight to ensure that the plans meet statutory, regulatory, and program requirements.[6] While the administrative and financial burden of the record keeping and reporting requirements of CMS may be daunting, it remains a necessary part of the Part D prescription drug process. It is possible, however, that the integration of HIT may make this process more efficient.

Looking Forward: The 2008 Summit

Medicare Part D is still in its infancy and will continue to develop as healthcare providers and payers respond to the challenges of changing technology, population characteristics, legislation, economics, and health care needs. Keeping an eye on the horizon and an awareness of market trends and drivers of change is imperative to effectively manage benefit designs and offerings for Part D beneficiaries. In response to this need, an additional Takeda-sponsored Part D Summit was conducted in July 2008 to discuss issues that could potentially alter how payers administer and manage their Part D programs. This meeting is a continuation of Takeda's ongoing initiative, the Managed Care Leaders Program, which is designed to focus on key issues and trends affecting payers. In follow up to the feedback collected during the first Part D Summit, this group focused on HIT and the overall management of Part D from a real-world perspective.
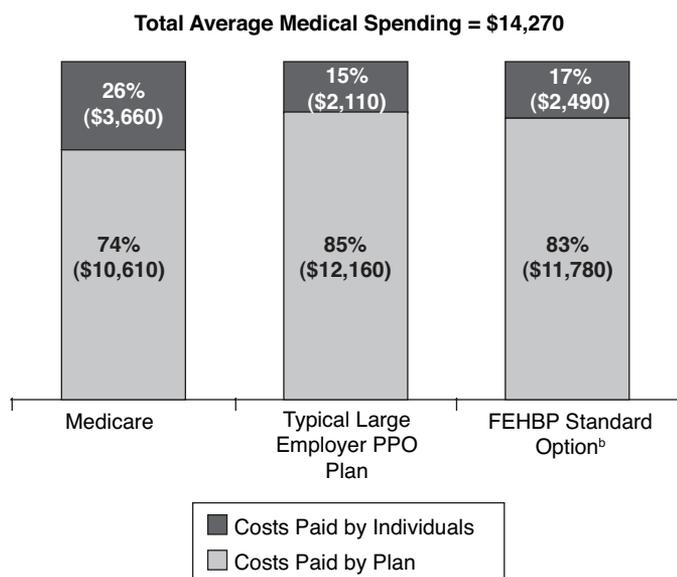
■ Current Management of Part D Benefits

The Medicare Part D drug benefit was enacted with a goal of providing access to prescription medications for all Medicare patients. Unique to this plan was dependence on private insurers and pharmacy benefit managers to provide coverage rather than having the government assume the role of insurer. As with many government programs, the intricacies of established regulations have brought about many changes throughout the health care industry. For health plans, negotiating these changes has been challenging. Plans are restricted by benefit design requirements and plan submission deadlines that eliminate a plan's flexibility to alter offerings in response to market changes. In some cases, the regulations contain ambiguous language that contributes to increased administrative burden. Cost-shifting to the beneficiary, as seen with the standard benefit and the doughnut hole, is becoming a more frequently used strategy to contain costs. CMS continues to evaluate Part D and is actively working to improve the quality of care for Part D beneficiaries through numerous demonstration projects.

Part D Today

The Part D benefit was established to assist with the payment of outpatient drug costs for the millions of Americans eligible for Medicare, and the anticipated benefits of Part D generated much excitement. Recently, the benefit value of the original FFS Medicare program, compared to the typical benefits offered by large employers, was evaluated in a report from the Henry J. Kaiser Family Foundation,[7] which suggests that Medicare is still lagging behind large employer plans. Employer plans were represented by the Blue Cross/Blue Shield (BCBS) standard nationwide preferred provider organization (PPO), available to federal employees through the Federal Employees Health Benefits Program (FEHBP), and a typical employer PPO plan. In this analysis, benefit values were assessed for participants who are eligible for Medicare because of age, not disability. Across the board, the Medicare benefit lags behind coverage provided by large employer plans. Overall, the average Medicare benefit value paid by plan and individuals varies from $1,000 to $1,500 less than that provided by the large employer groups (Figure 1). For prescription plans, Medicare pays a lower percentage of prescription drug costs compared to employer plans (Figure 2). Beneficiary cost-sharing for the prescription drug benefit was higher with the Medicare plan with average prescription drug plan payments for Medicare at $1,590 compared to $2,270 to $2,500 for the large employer plans included in this analysis.[7]

FIGURE 1 Benefit Value and Share of Total Costs Paid by Plan and Individual Payments Under Medicare and Employer Plans in 2007 Favor the Large Employer Plans[a]
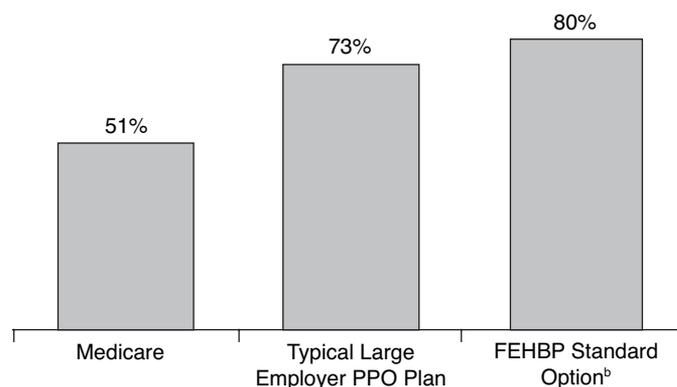
Total Average Medical Spending = $14,270

Medicare	Typical Large Employer PPO Plan	FEHBP Standard Option[b]
26% ($3,660)	15% ($2,110)	17% ($2,490)
74% ($10,610)	85% ($12,160)	83% ($11,780)

■ Costs Paid by Individuals
□ Costs Paid by Plan

[a]*Excerpted from Yamamoto D, Neuman T, Strollo M.[7] The Henry J. Kaiser Family Foundation, September 2008. This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation is a non-profit private operating foundation, based in Menlo Park, California, dedicated to producing and communicating the best possible information, research, and analysis on health issues.*
[b]*The FEHBP (Federal Employees Health Benefits Program) standard option is offered through Blue Cross Blue Shield. Employer plans include dental benefits.*
Source: Hewitt Associates analysis for the Kaiser Family Foundation, 2008.[7]

FIGURE 2 Medicare Paid a Lower Percentage of Prescription Drug Costs in 2007 Compared to Employer Plans[a]

Medicare	Typical Large Employer PPO Plan	FEHBP Standard Option[b]
51%	73%	80%

[a]*Excerpted from Yamamoto D, Neuman T, Strollo M.[7] The Henry J. Kaiser Family Foundation, September 2008. This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation is a non-profit private operating foundation, based in Menlo Park, California, dedicated to producing and communicating the best possible information, research, and analysis on health issues.*
[b]*The FEHBP (Federal Employees Health Benefits Program) standard option is offered through Blue Cross Blue Shield. Employer plans include dental benefits.*
Source: Hewitt Associates analysis for the Kaiser Family Foundation, 2008.[7]

In an effort to control health care spending through the years, CMS has consciously worked to increase beneficiary participation in managed Medicare plans instead of FFS plans. Following the Balanced Budget Act of 1997, Medicare+Choice plans were developed to provide Medicare recipients another option for health care coverage. In general, Medicare+Choice plans provided benefit coverage that paralleled traditional Medicare without incurring additional costs to the beneficiary. Medicare paid a fixed amount to the plan for each enrollee. Any cost savings realized by providing services at a cost lower than the Medicare payment level were distributed to beneficiaries by reductions in premiums and copayments or additional benefits.[8] While there were a number of different Medicare+Choice plans available, the most common plan type was an HMO, and most included prescription drug coverage. Despite initial enthusiasm for this type of coverage, enrollment began to decline between 2000 and 2003, the final year of Medicare+Choice.[9] By 2003, enrollment in Medicare+Choice had fallen to only 11% of the Medicare population (4.6 million beneficiaries), and the number of plans partici-

pating fell by 50%.[8] By comparison, 8 million of the 44 million eligible Medicare beneficiaries (18%) are enrolled in Medicare Advantage-Prescription Drug (MA-PD) plans. Medicare+Choice plans served as a rough template for the current MA programs—Medicare+Choice became MA in 2003. Along with the conversion from Medicare+Choice to MA, the development of the prescription benefit under Part D, and the inception of Prescription Drug Plans (PDPs), MCOs were faced with increased regulatory oversight from CMS. These changes have resulted in less flexibility for plans with higher overall cost outlays for patients. There was unanimous agreement among Summit participants that the current Part D benefit places significant restrictions on plans that were not evident with the drug benefit requirements under the Medicare+Choice program. Concerns regarding how these limits will impact patient satisfaction continue to be raised.

Most of the Summit meeting participants voiced concerns about the amount of time that is spent on administrative tasks necessary to meet requirements of the Part D program. In a random survey of 1,183 psychiatrists during the first 4 months of Medicare Part D, these physicians reported that an additional 45 minutes was spent on administrative tasks for each 1 hour of direct patient care for dually eligible patients.[10] Some specific Medicare Part D plan characteristics (prior authorization, preferred drug list, dosing limits) led to significant ($P<0.01$) variations in administrative time per hour of patient care between

plans with those features and those without. The administration time for handling prescription drug plan features ranged from 44 minutes to 71.4 minutes. Time spent on prescription drug administration—problems filling prescriptions (61.9 minutes vs. 8.6 minutes, *P*<0.01) and appeals request initiation (62.1 minutes vs. 10.5 minutes, *P*<0.05)—as well as difficulties with medication access also contributed to the significant administrative burden.[10] Although this analysis was done for dually eligible patients and only reflects the first few months following widespread implementation of the Part D program, the administrative burden for other patient populations remains uncertain.

Key Challenges Faced by MA/PDP Plans

Benefit designs are a key component in population management strategies. Innovative designs are often used in the commercial sector to drive healthy behaviors (e.g., well visits, preventative care, drug adherence, etc.) and to differentiate plans from competitors within the markets they serve. Summit participants agreed that current CMS regulations impinge on the flexibility of benefit designs, restricting the development of new programs and creating barriers to price negotiations.

Other regulations exist that have an impact on the design of programs geared at improving patient adherence. One way some plans entice patients to adhere to treatment regimens is to offer incentives. However, the language that is contained in the current regulations is ambiguous and plans are reluctant to initiate benefit design changes, including incentives such as lowered copayments, because they fear the government will take action against them. For example, statements such as "substantially fail to provide an enrollee with medically necessary items and services" and "engage in certain marketing, enrollment…or do not meet the requirements for physician incentive plans" are difficult to interpret.[11] The ability of plans to effectively compete and improve the quality of care requires better definition of current regulations so that plans are confident that possible benefit design changes are within regulatory boundaries.

Further, current CMS regulations require months in advance to approve new initiatives for plans participating in Part D. To provide a drug benefit in the following calendar year, plans must submit bids for provision of a drug benefit for the following calendar year prior to the first Monday in June of the current year.[12] This lag time does not permit plans to account for changes in the second half of the year that may affect utilization or pricing. In addition, MA plans are now prohibited from making changes to coverage of nonprescription medications and cost-sharing midyear.[13] Previously, CMS allowed these midyear changes. The change was implemented, in part, to maintain the integrity of the bidding process.

Drug Formularies

Formulary management has been one of the tools that health plans use to contain the rising costs of medications. Formulary requirements for the Part D benefit are restrictive and include mandates for coverage of at least 2 medications within each Part D-covered therapeutic class. There are also 6 categories of medications that are essentially considered full access—antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs.[12] All medications within these categories must be included on each plan's formulary. For many categories of medications, these stipulations prohibit competitive price negotiations for drugs within a class. Essentially, it provides open access to these therapies.

Since the introduction of the Part D benefit, there has been confusion regarding coverage of drugs under Part B and Part D. Vaccines and erythropoietin represent examples of therapeutic categories affected by coverage questions.[12] Recent CMS changes have attempted to clarify coverage concerns. Plans are now required to include all vaccines not covered under the Part B benefit in the offerings under Part D.[14] For some chronic diseases, such as end-stage renal disease, whether coverage for medications, such as erythropoietin, should be obtained through Part D or Part B remains a source of confusion and adds to the complexity of care.

The "Doughnut Hole"

Another unique feature of the Part D standard benefit is the existence of the "doughnut hole." The doughnut hole represents the coverage gap between the level at which the patient is responsible for 100% of drug costs until they meet the requirements for catastrophic coverage.[9] This totaled $3,051 in 2007, with total out-of-pocket costs drug costs of $3,850, before beneficiaries were eligible for catastrophic coverage.[15] In 2007, 26% of beneficiaries who did not qualify for low-income subsidies (LIS) reached the coverage gap.[9] Most of these individuals remained in the gap and never qualified for catastrophic coverage. The coverage gap places significant financial burden on the beneficiary; this burden is expected to continue to increase as the dollar value of the coverage gap is expected to double by 2017.[15]

The doughnut hole was created as part of the provision of the defined standard benefit. Only about 10% of PDPs offered the standard benefit in 2007.[16] Tiered, flat-rate copayments are a more common type of coverage provision. Yet, the coverage gap remains a significant cost burden for some patients. Only 29% of PDPs and 51% of MA-PDs offered any type of gap coverage in 2008—most coverage was limited to generic drugs.[16] Coverage for generic medications in the doughnut hole is typically limited to certain medications. One stand-alone PDP and 17% of MA-PDs provided gap coverage for some brand name drugs. Almost all of the plans represented by Summit participants provide coverage for the doughnut hole; this coverage is limited to tier 1 medications and generics.

Arguments can be made both for and against the coverage gap. The existence of the doughnut hole increases the stake that patients have in using low-cost medications and may help to

control rapidly rising health care spending. However, for many chronic diseases, new therapies that may offer therapeutic advantages are not available in a generic formulation. Patients requiring these types of medications may reach the gap more quickly, creating a disincentive for adhering to chronic medications. In fact, 20% of enrollees receiving proton pump inhibitors, antidepressants, oral antidiabetic medications, osteoporosis medications, ACE inhibitors, statins, angiotensin receptor blockers, or Alzheimer's disease treatments reached the coverage gap in 2007 and then altered their medication use. Patients stopped the medication (15%), reduced their medication use (1%), or switched to an alternative drug (5%).[15] These effects may be greater considering that only 8 classes of medication were included in this study. The long-term implications of discontinuation or switching therapy remain unknown and have the potential to increase total health care costs. This effect has been previously seen under the Medicare+Choice benefit and warrants close monitoring with Part D beneficiaries. In an analysis of more than 150,000 Medicare+Choice participants with a $1,000 prescription drug benefit cap and almost 42,000 whose drug benefits were unlimited in 2003, the cap on drug benefits was associated with a reduction in drug consumption.[17] For antihypertensive medications, consumption decreased 15% (95% CI=11.4%-18.1%) among those whose benefits were capped. This decrease in consumption was also seen for lipid lowering agents (27% reduction in consumption, 95% CI=23.1%-30.4%) and antidiabetic agents (21% reduction, 95% CI=14.3%-26.6%). The benefit cap was also associated with a lower adherence to drug therapy in patients with chronic diseases (Figure 3). In this evaluation, increased costs of hospitalization and emergency department care negated any financial savings in drug costs. When benefits were capped, pharmacy costs were 28% lower (95% CI=25.6%-30.4%) compared to uncapped benefits. However, hospital costs were 13% higher (95% CI=1.3%-26.5%) and emergency department charges were 9% higher (95% CI=1.0%-17.7%) for those with capped benefits. There was no significant difference between the groups with respect to total health care costs for the measurement year (2003).[17]

The Benefits of CMS Involvement

The provision of high quality, evidence-based care is an essential component of efforts to reduce overall health care costs. Through the many demonstration projects sponsored by CMS, it is hoped that the data generated will serve to determine the best approaches for delivery of high-quality, cost-efficient care. While these changes are evaluated in the Medicare setting, if the innovations prove valuable the results could easily be translated to the larger managed care market. Essentially, CMS is helping the managed care industry by "test-marketing" potential system changes. CMS has more than 50 demonstration projects underway revealing a commitment to improvements in health care provision (Table 1).[18]

FIGURE 3 Drug Nonadherence Was Higher for Subjects With a Benefit Cap Compared With Those With Uncapped Benefits[a,b]
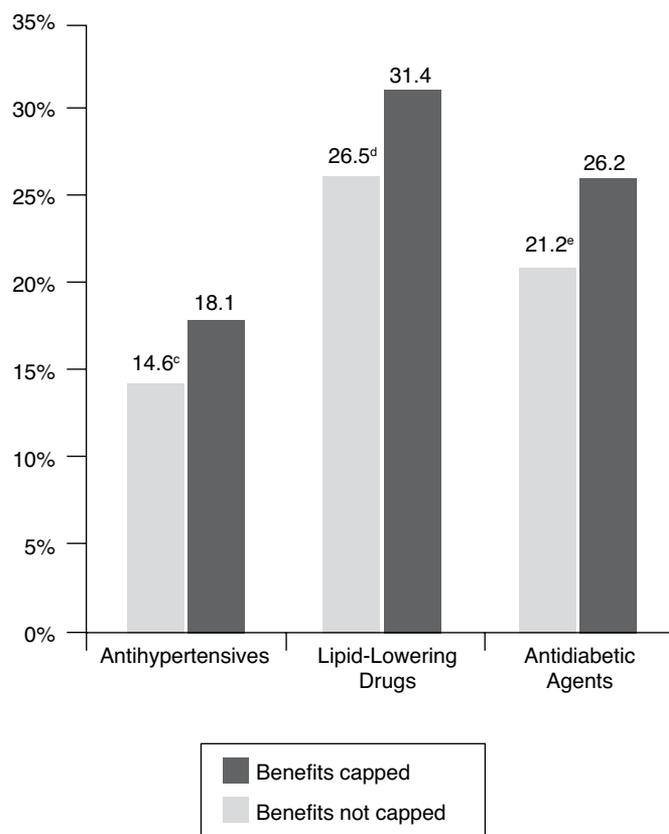
[a]*Adapted from Hsu J, Price M, Huang J, et al. N Engl J Med. 2006;354(22):2349-59.[17]*
[b]*Medicare+Choice beneficiaries aged ≥ 65 years enrolled in a 2-tier benefit plan (N = 157,275 with annual drug benefits capped at $1000, and N = 41,904 without benefit cap).*
[c]*Odds ratio 1.30, 95% CI = 1.23-1.38.*
[d]*Odds ratio 1.27, 95% CI = 1.19-1.34.*
[e]*Odds ratio 1.33, 95% CI = 1.18-1.48.*

One such project is the Care Management for High Cost Beneficiaries Demonstration project, designed to evaluate whether provider-based intensive care management services improve quality of care and decrease costs for FFS beneficiaries with 1 or more chronic diseases.[19] Six organizations are participating in this 3-year demonstration project that, for most, began in 2006. It is hoped that through this project, effective cost-management strategies can be identified for the 15% of FFS participants who consume 75% of the total Medicare expenditures in any given year.

Another demonstration project that could lead to significant changes in health care practices is the EHR demonstration project.[20] The acceptance of EHRs has been slow and has met with

TABLE 1   Numerous CMS Demonstration Projects Highlight Commitment to Improving Quality of Care[a]

Demonstration Project Name	Demonstration Type	Year
Medicare Acute Care Episode (ACE) Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2009
Electronic Health Records Demonstration	Upcoming Demonstrations	2008
Medicare Medical Home Demonstration	Upcoming Demonstrations	2007
Home Health Pay for Performance Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2007
Medicare Part D Payment Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2007
DRA 5007 Medicare Hospital Gainsharing Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2006
MMA Section 646 Physician Hospital Collaboration Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2006
Frontier Extended Stay Clinic Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2006
Medicare Care Management Performance Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2006
Senior Risk Reduction Program	Solicitation Period Closed/Ongoing Demonstrations	2006
Medicare Low Vision Rehabilitation Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2006
Post Acute Care Payment Reform Demonstration	Active Demonstrations Accepting Enrollments	2006
Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities	Solicitation Period Closed/Ongoing Demonstrations	2005
Frequent Hemodialysis Network Clinical Trials	Solicitation Period Closed/Ongoing Demonstrations	2005
Care Management for High-Cost Beneficiaries Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2005
Demonstration Project for Medical Adult Day Care Services	Solicitation Period Closed/Ongoing Demonstrations	2005
MMA 623 ESRD Bundled Payment Demonstration	Upcoming Demonstrations	2005
Nursing Home Value-Based Purchasing	Upcoming Demonstrations	2005
The Medicare Replacement Drug Demonstration	Completed Demos & Evaluation Reports	2005
MMA Demonstrations List	MMA Demonstrations List	2005
Recovery Audit Contractors	Solicitation Period Closed/Ongoing Demonstrations	2005
MMA 646: Medicare Health Care Quality Demonstration Program	Solicitation Period Closed/Ongoing Demonstrations	2005
Medicare Home Health Independence Demonstration	Completed Demos & Evaluation Reports	2004
MMA Section 651 Expansion of Coverage of Chiropractic Services Demonstration	Completed Demos & Evaluation Reports	2004
Rural Community Hospital Demonstration Program	Open Solicitation Demonstrations	2004
Demonstration Project for Competitive Bidding of Clinical Laboratory Services	Upcoming Demonstrations	2004
Evaluation of DoD Subvention Demonstration	Completed Demos & Evaluation Reports	2004
Demonstration Project for Consumer-Directed Chronic Outpatient Services	Upcoming Demonstrations	2003
Medicare BIPA Disease Management Demonstration	Completed Demos & Evaluation Reports	2003
Rural Hospice Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2003
ESRD Disease Management Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2003
Premier Hospital Quality Incentive Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2003
Evaluation of the Community Nursing Organization Demonstration	Completed Demos & Evaluation Reports	2003
Evaluation of Medicare Preferred Provider Organization Demonstration	Completed Demos & Evaluation Reports	2003
Evercare Demonstration	Completed Demos & Evaluation Reports	2002
Medicare Partnerships for Quality Services Demonstration	Completed Demos & Evaluation Reports	2002
Demonstrations Serving Those Dually - Eligible for Medicare and Medicaid	Solicitation Period Closed/Ongoing Demonstrations	2002
Evaluation of the Social Health Maintenance Organization Demonstration (SHMO)	Completed Demos & Evaluation Reports	2002
End-Stage Renal Disease Managed Care Demonstration	Completed Demos & Evaluation Reports	2002
Medicare Stop Smoking Program	Completed Demos & Evaluation Reports	2002
Medicare Coordinated Care Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2001
Private, For-Profit Demo Project for the Program of All-Inclusive Care for the Elderly (PACE)	Open Solicitation Demonstrations	2001
Evaluation of the Home Health Agency Prospective Payment Demonstration	Completed Demos & Evaluation Reports	2001
Evaluation of the Durable Medical Equipment Competitive Bidding Demonstration	Completed Demos & Evaluation Reports	2000-2004
Medicare Physician Group Practice Demonstration	Solicitation Period Closed/Ongoing Demonstrations	2000
Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration Project	Solicitation Period Closed/Ongoing Demonstrations	2000
Medicare Preventive Services - Medicare Lifestyle Modification Program Demonstration	Completed Demos & Evaluation Reports	1999
Evaluation of PACE Demonstration	Completed Demos & Evaluation Reports	1998
Medicare Participating Heart Bypass Center Demonstration	Completed Demos & Evaluation Reports	1998
Evaluation of the Medicare Choices Demonstration	Completed Demos & Evaluation Reports	1997
Evaluation of Medicare Case Management (Early Coordinated Care) Demonstrations	Completed Demos & Evaluation Reports	1995

[a]Derived from Centers for Medicare & Medicaid Services. Medicare Demonstrations.[18]

much resistance from practitioners, yet there is potential for this technology to improve the quality of care. Undertaken to foster the implementation and adoption of EHRs and HIT, it is hoped that by tapping both private and public payers, physician practices will be driven to adoption of these technologies.

■ Conclusion

The intent of the Medicare Part D benefit was to provide prescription drug coverage for the elderly, as well as non-elderly chronically disabled Medicare beneficiaries. In lieu of government-negotiated pricing for medications, a system was developed that relied on competitive marketing among plans to hold down health care costs. The rules and regulations that have accompanied the enactment of the Part D benefit may negatively affect the flexibility of plans. The rules and regulations increase administrative burden, do not allow flexibility when submitting health plan bids, and in some cases contain ambiguous language that creates confusion among plan administrators. The doughnut hole remains a major concern with beneficiaries experiencing the economic pinch of significant cost-shifting and for plans that are looking to better manage long-term costs by driving appropriate medication use and increased adherence. While many of these CMS mandates can be burdensome for MCOs, the potential for identifying opportunities to improve the quality of care through other CMS initiatives such as demonstration projects and directives for adoption of HIT is exciting.

REFERENCES

1. Cammisa CR, Evans S, Fenter TC, et al. Overview of current Medicare Part D offerings. *J Manag Care Pharm.* 2008;14(6)(supp s-c):S4-S7. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C_S4-S7.pdf.

2. Gonzalez J, Noga M. Medication therapy management *J Manag Care Pharm.* 2008;14(6)(suppl S-c):S8-S11. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C_S8-S11.pdf.

3. Cammisa CR. Special needs plans. *J Manag Care Pharm.* 2008;14(6)(suppl S-c):S19-S21. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C-All.pdf.

4. Fenter TC, Lewis SJ. Pay-for-performance initiatives. *J Manag Care Pharm.* 2008;14(6)(suppl S-c):S12-S15. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C_S12-S15.pdf.

5. Evans S, Stemple C. Electronic health records and the value of health IT. *J Manag Care Pharm.* 2008;14(6)(suppl S-c):S16-S18. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C_S16-S18.pdf.

6. Lee H. CMS oversight. *J Manag Care Pharm.* 2008;14(6)(suppl S-c):S22-S24. Available at: www.amcp.org/data/jmcp/Aug%20suppl%20C_S22-S24.pdf.

7. Yamamoto D, Neuman T, Strollo M. How does the benefit value of Medicare compare to the benefit value of typical large employer plans? Available at: www.kff.org/medicare/upload/7768.pdf. Accessed October 6, 2008.

8. Kaiser Family Foundation. Medicare and prescription drugs. Fact Sheet April 2003. Available at: www.kff.org/medicare/upload/Medicare-and-Prescription-Drugs-Fact-Sheet-Fact-Sheet.pdf. Accessed December 18, 2008.

9. Gold M, Achman L, Mittler J, Stevens B. Monitoring Medicare+Choice: What have we learned? Findings and operational lessons for Medicare Advantage. Available at: www.mathematica-mpr.com/publications/PDFs/monitor.pdf. Accessed October 13, 2008.

10. Wilk JE, West JC, Rae DS, Rubio-Stipec M, Chen J, Regier D. Medicare Part D prescription drug benefits and administrative burden in the care of dually eligible psychiatric patients. *Psychiatr Serv.* 2008;59(1):34-39.

11. Office of the Inspector General. Health care, Department of Health and Human Services. 42 CFR Ch IV. Available at: www.access.gpo.gov/nara/cfr/waisidx_07/42cfrv4_07.html. Accessed October 8, 2008.

12. Atlantic Information Services Inc. *Medicare Part D: A Comprehensive Analysis of CMS Rules.* Washington, DC: Atlantic Information Services, Inc; 2008.

13. Pharmasentry. Medicare program: prohibition of midyear benefit enhancements for Medicare Advantage organizations. Available at: www.pharmasentry.com/news/newsletter.cfm?linkID=774F75C8-1372-54C2-6137B94665D5123B. Accessed July 31, 2008.

14. DePue R, Stubbings J. Medicare Part D: selected issues for plan sponsors, pharmacists, and beneficiaries in 2008. *J Manag Care Pharm.* 2008;14(1):50-60. Available at: www.amcp.org/data/jmcp/JMCPMaga_JanFeb%2008_050-060.pdf.

15. Hoadley J, Hargrave E, Cubanski J, Neuman T. The Medicare Part D coverage gap: costs and consequences in 2007. Henry J. Kaiser Family Foundation. Available at: www.kff.org/medicare/upload/7811.pdf. Accessed September 22, 2008.

16. Hoadley J, Hargrave E, Cubanski J, Neuman T. Medicare prescription drug plans in 2008 and key changes since 2006: summary of findings. Henry J. Kaiser Family Foundation. Available at: www.kff.org/medicare/upload/7762.pdf. Accessed September 22, 2008.

17. Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. *N Engl J Med.* 2006;354(22):2349-59.

18. Centers for Medicare & Medicaid Services. Medicare demonstrations. Available at: www.cms.hhs.gov/includes/dynamiclist/excel.asp?filtertype=none&pathinfo=/demoprojectsevalrpts/MD/list.asp&sortOrder=descending&filterByDID=-99&intNumPerPage=2000&excel=1. Accessed October 8, 2008.

19. Centers for Medicare & Medicaid Services. Care management for high-cost beneficiaries demonstration project. General information fact sheet. Available at: www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMHCB_GeneralInfo_FactSheet.pdf. Accessed October 8, 2008.

20. Centers for Medicare & Medicaid Services. Electronic health records (EHR) demonstration. Demonstration summary. Available at: www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/EHR_DemoSummary.pdf. Accessed September 21, 2008.

Health Information Technology—
Results From a Roundtable Discussion

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ABSTRACT

BACKGROUND: Health information technology (HIT), notably e-prescribing and electronic health records (EHR), have the potential to improve the quality of care, reduce medication errors and adverse events, and decrease overall health care utilization and costs. However, the United States continues to lag behind other countries in the adoption and use of HIT.

OBJECTIVE: To review the various issues surrounding the implementation of HIT in the United States and potential drivers that will influence the use of e-prescribing and EHR.

SUMMARY: The United States has been slow to embrace HIT. However, various factors, including increasing government involvement, are speeding the implementation and use of HIT. E-prescribing and EHR are both electronic means to provide better coordination of care by enabling various health care professionals to access patient medical records. Widespread adoption of HIT can be especially helpful for the elderly, since this population tends to have more chronic conditions requiring polypharmacy. Adoption of e-prescribing can reduce medication errors due to poor handwriting, while EHR can promote better clinical outcomes, improve medication adherence and refill rates, improve member satisfaction, and lower overall health care expenditures. Unfortunately, barriers to the adoption of e-prescribing and EHR still exist, including resistance to learning new technology, initial start-up costs, delay in seeing a return on investment, lack of a standardized platform, increased administrative burden, and misaligned incentives. In an effort to promote greater adoption of e-prescribing and EHR, the Centers for Medicare & Medicaid has designed several initiatives, and other private organizations are now becoming more involved to close the HIT gap.

CONCLUSION: Although the United States has been slow to implement HIT, there is reason to be hopeful. Increasing involvement by the government and other organizations will facilitate the greater adoption and use of e-prescribing and EHR in the near future. Ongoing data are needed, however, to demonstrate improvements in overall patient care and reductions in health care utilization and costs. These data are necessary to remove existing barriers that may prevent widespread implementation.

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Health information technology (HIT), the secure transmission and management of health information, is relatively new. Despite its availability, acceptance and use of HIT in the United States has been slow and lags behind many industrialized countries.[1] Forces within the current environment—rising health care expenditures, high adverse event rates, and government and private initiatives—are increasing the speed of acceptance of HIT. Challenges to the adoption of HIT in the United States have included the high costs of the technology, general resistance to change, misaligned incentives, and the fractured payment system. Believing that HIT will improve the quality and safety of health care, President George W. Bush set a goal for most Americans to have an electronic health record (EHR) by 2014.[2] The Centers for Medicare & Medicaid Services (CMS) has followed through on this directive by instituting programs aimed at increasing the adoption and use of HIT, starting with e-prescribing and EHR.

■ Benefits of HIT

Increased use of HIT can benefit all members of the health care system: patients, payers, prescribers, physicians, office staff, and pharmacies.[3] While one particular technology may provide a more apparent benefit to a particular segment, the overall improvement in patient care that can be realized affects all stakeholders in the process.

Improvements in Quality of Care

Data drive the measurement of quality in health care. Collecting data can be cumbersome in a paper and pencil world. Capturing information electronically is a major asset of HIT and facilitates quality measurement. Data that are mined through HIT applications provide continuous feedback to providers and plans and are an invaluable tool for guiding future care decisions.

E-prescribing

E-prescribing uses technology to allow prescribers to electronically transmit prescriptions. The intent of this technology is to reduce medication errors and improve patient care by eliminating the need for interpreting handwritten prescriptions.[4] Through the increased use of e-prescribing, physicians have the benefit of receiving real-time formulary, drug-drug and drug-allergy information as well as a history of drugs dispensed for the patient. The elimination of handwriting interpretation decreases medication error rates and reduces communication time between pharmacies and office staff. Payers are better able to promote increased utilization of generic and preferred brand drugs, as well as avoid costs resulting from adverse drug events. However,

even with electronic prescribing, errors in drug selection, dose, and duration of therapy may occur. Since e-prescribing is still relatively new, its overall impact on medication errors will need to be closely watched.

EHR

EHR provides immediate electronic access to information at both a patient and population level and supports clinical decision making and additional information that can enhance the quality and safety of patient care. EHRs may be maintained by providers or individuals (also known as personal health records [PHRs]). However, a precise and consistent description of a fully functional EHR system remains elusive, which makes interpretation of the published literature difficult. According to the Institute of Medicine (IOM), EHRs should have 8 core care-related functionalities: health information and data, result management, order management, decision support, electronic communication and connectivity, patient support, administrative processes, reporting and population health management.[5]

According to a review by the Agency for Healthcare Research and Quality (AHRQ), EHR applications improve quality of care.[6] A total of 84 papers related to EHRs were identified; those meeting criteria (n=7) for functionality and the ambulatory setting were included in the final analysis. The authors concluded that there is support in the literature for improvement in provider performance when clinical support decision-making tools (e.g., prompts for preventive medications, screening for drug interactions) are part of the EHR system. The key to the success of improving performance is the accessibility of data and the ability to translate the data into information that a provider can use to improve clinical practice.[6]

Improvements in care coordination also require access to data. Patients with chronic conditions or multiple comorbid conditions often have many caregivers, require multiple medical tests, and take more than one medication. Sharing patient-related information among caregivers is often difficult and may be unrealistic if the patient has treatment records in a variety of settings (e.g., hospitals, clinics, private practice). The use of an EHR could simplify the coordination of care and streamline access to patient medical records.

The Veterans Health Administration (VHA) is often cited as a model for the provision of coordinated care. Through the promotion of EHR and the use of outcomes indicators, the VHA strives to constantly improve care for veterans. Following the implementation of an integrated electronic medical record (EMR), males ≥35 years of age from a VHA cohort were compared to a random sample of men from 12 communities in a study using a subset of quality indicators (n=348) from RAND's Quality Assessment Tools system, which represents both inpatient and outpatient care for acute and chronic conditions.[7] The VHA cohort (n=596) scored significantly higher than the national sample cohort (n=992) for adjusted overall quality (67% vs. 51%, respectively [95% CI=14%-18%]), chronic disease care (72% vs. 59%,

respectively, [95% CI=10%-17%]), and preventive care (64% vs. 44%, respectively [95% CI=12%-28%]). Differences between the cohorts were greatest when the care process was also part of the VHA performance measurement system.

The impact of HIT on delivery of patient care was the focus of a recent systematic literature review that included 257 studies.[8] The benefits of HIT fell into 3 main groupings: increased adherence to guidelines or protocols, improved medication safety, and enhanced surveillance and monitoring. The majority of systems included in these studies were decision-support systems aimed at providers (63%) with 37% of studies evaluating EHR. Use of EHR was more common in the outpatient setting, and provider order entry systems were more common in the inpatient setting. Promoting increased adherence to guidelines or protocols was considered the major impact of HIT. Absolute increases in improvements in quality of care ranged from 5% to 66% with most increases found in the range of 12% to 20%. Improvements in primary preventive measures with the use of HIT also occurred. Reductions in medication errors were noted in results from 4 studies, and improvements in systems evaluations focused mainly on prevention of disease outbreaks. The review also evaluated the effects of HIT on efficiency. Most of the studies (80%) that evaluated the effect of HIT systems on utilization of care and provider time showed decreased rates of health services utilization such as diagnostic tests and laboratory measurements.[8]

■ Impact on Cost

Health information exchanges involve sharing of clinical, financial, and demographic data among health care stakeholders in support of care delivery, financing, public health surveillance, research, and other health system activities. According to a September 2008 survey by eHealth Initiative,[9] most fully operational information exchange systems (29/42, 69%) reported a reduction in costs. These reductions were realized through improvements in quality of care such as avoidance of redundant tests; avoidance of hospital admissions for medication allergies, errors, or interactions; lower costs of care for patients with chronic conditions; and reductions in time spent on administration. The majority of respondents cite securing up-front funding as a significant challenge.[9] Additionally, of the 130 respondents, 82% said that as a sustainable business model, HIT was a very difficult or moderately difficult challenge.

E-prescribing

With e-prescribing, it is hoped that the improved safety and accuracy of prescribing will translate to better patient outcomes and reductions in personnel time required for prescription clarification.[10] Savings in personnel time both from a prescribing and dispensing perspective could exceed $400 million. CMS estimates that over a 5-year period, the economic benefit of e-prescribing achieved by prescribers, dispensers, and beneficiaries could exceed $800 million.[10]

Overall Health Care Costs Per Patient By Year—Lower With EHR Use in a VHA Population (No EHR use in Medicare Comparator)[a]
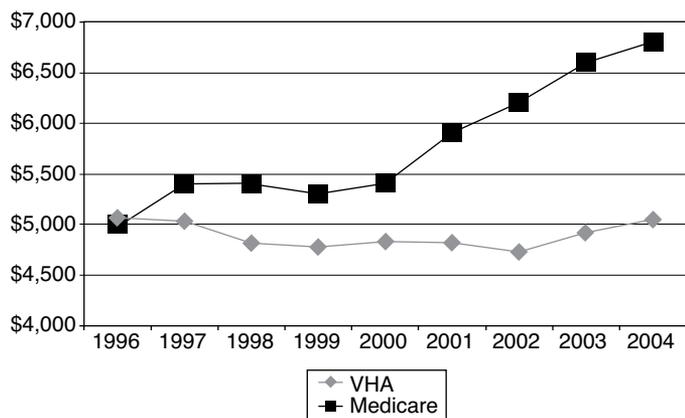
[a]Used with permission from Evans D, Nichol W, Perlin J. Health Econ Policy Law. 2006;1(Pt.2):163-69.[14]

FIGURE 2 Annual E-prescription Transactions Are on the Rise[a]

[a]Excerpted from The National Progress Report on E-Prescribing, 2007, Pharmacy Health Information Exchange, operated by SureScripts (December 2007).[15]
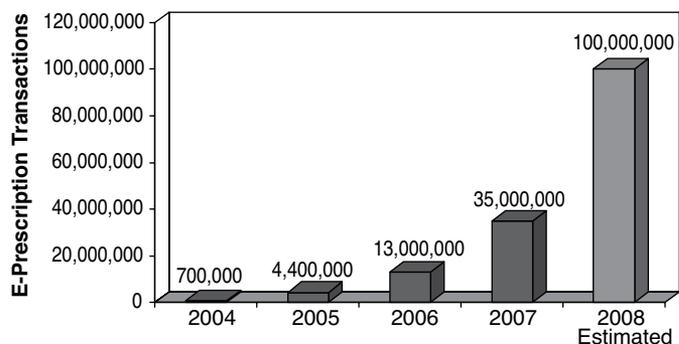
EHR

Although cost is often cited as a barrier to adoption of EHR, several studies indicate that start-up costs are often balanced with cost savings, resulting in a cost-neutral change.[11-13] In a model framed from the perspective of the health care organization, EHR costs were compared to traditional paper-based medical records for a 5-year period.[13] Both system costs (software, implementation, support and maintenance, hardware) and induced costs (costs stemming from an initial loss of productivity due to new processes) were included in the model. Benefits included costs avoided and increases in revenue generation. Despite an annual cost of $46,400 (in 2002 dollars) associated with EHR, an annual benefit of $154,900 was realized when EHR was implemented.[12,13]

Improvements in productivity have been noted following implementation of an in-house EHR.[14] In the VHA, a shift to EHR from 1996 to 2004 was accompanied by an increase in the number of patients treated (69.4%) and a net decrease of 23.3 full-time employee equivalents per 1,000 patients (37% reduction). Implementation of the EHR system at the VHA also enabled the provision of care at an overall cost per patient that was 26% lower than Medicare's cost per patient (Figure 1).[14]

Retrospective qualitative case studies of 14 solo or small-group primary care practices were conducted to determine the costs and benefits of EHRs.[12] Costs were based on one-time and ongoing EHR-related expenses as well as productivity loss, training needs, and telecommunications. Average costs per full-time equivalent provider per year were $43,826 initially, with ongoing costs averaging $8,412. Average benefits per full-time equivalent

provider per year were $32,737; thus, approximately $23,000 in net benefits per full-time equivalent provider per year were realized within two and one-half years of EHR use.[12]

■ Current Status of HIT

While the benefits of HIT adoption have been demonstrated, its acceptance and use in the United States has not kept pace with the world at large. Adoption rates for different HIT applications are varied but overall remain low. eHealth Initiative conducts an annual survey to gauge HIT penetration in the U.S. market. According to the 2008 survey, the number of fully operational health information exchange initiatives in the United States increased 31% (from 32 in 2007 to 42 in 2008).[9] This figure highlights the low adoption rate but offers hope that the tide may be turning.

E-prescribing

E-prescribing is expected to reach the 100 million mark in 2008, reflecting 7% of all eligible prescriptions (new and renewal transactions) (Figure 2).[15] In 2007, there were approximately 35,000 prescribers employing e-prescription technology and the number of e-prescribers is expected to more than double to 85,000 by the end of 2008. While an increase is expected, physician use of e-prescribing in the United States still lags behind many other countries (Figure 3).[1]

EHR

As with e-prescribing, the adoption of EHR in the United States trails many other countries.[1] DesRoches et al.[16] described the state of EHR adoption in 2007 and 2008 by conducting a national survey of 2,758 physicians (62% response rate; Figure 4). Physicians were identified from the 2007 Physician Masterfile of the American Medical Association. Overall, the adoption rate

FIGURE 3 United States Lags Behind in the Adoption of Electronic Medical Records and E-prescribing[a]
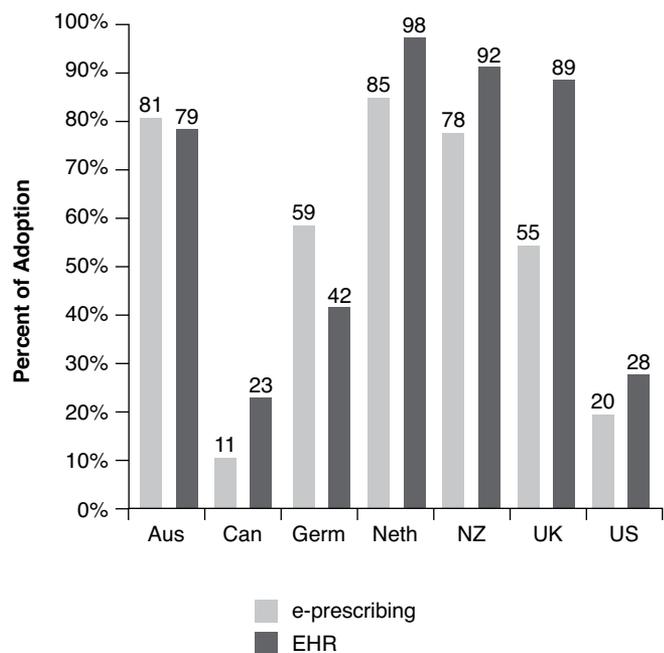
[a]Adapted from The Commonwealth Fund 2006 International Health Policy Survey of Primary Care Physicians in Seven Countries.[1]

was low, with only 4% of physicians reporting that they used a fully functional EHR system. A basic system was used by 13% of surveyed physicians. Primary care physicians utilized this technology more often than physicians who are not in primary care practices ($P<0.001$). Adoption of EHR was higher if the practice was associated with a hospital or medical center ($P=0.008$). Larger physician practices were also more likely to utilize EHR than small practices ($P<0.001$). Physicians with a fully functional system were more likely to be satisfied with the reliability of the technology than physicians with a basic system (90% vs. 79%, $P<0.01$). Overall, a positive response to survey questions regarding the beneficial effects of EHR on their practice was more frequently reported by physicians who used a fully functional system (Figure 4). Financial incentives for technology purchases and payment for use of the EHR system were cited as facilitators of adoption.[16]

■ **Pushing HIT Adoption Forward**

Major efforts are underway to increase HIT adoption. The cost of health care is skyrocketing; for 2007, total spending for health care was $2.3 trillion, representing 16% of the U.S. gross domestic product (GDP).[17] Health care expenditures for the United States exceed health spending in other countries even though

health care benefits are not offered to all U.S. citizens. These costs are expected to continue to grow; at the current rate of growth, health care is expected to reach 20% of the GDP within a decade.[17] Means to provide high quality care at the lowest cost continues to spur the use of technology forward. When technological advances improve care and prevent medical misadventures, costs reductions are realized.

High rates of medication errors and adverse events related to treatment are also driving the push for adoption of HIT. The Institute of Medicine Report *To Err Is Human* has been instrumental in pushing issues of patient safety to the forefront of public discussions.[18] Each year, medication errors alone are responsible for an estimated 1.5 million injuries and $3.5 billion in excess costs.[19] Increased use of HIT is often cited as one key component of reducing this high error rate and the associated costs.
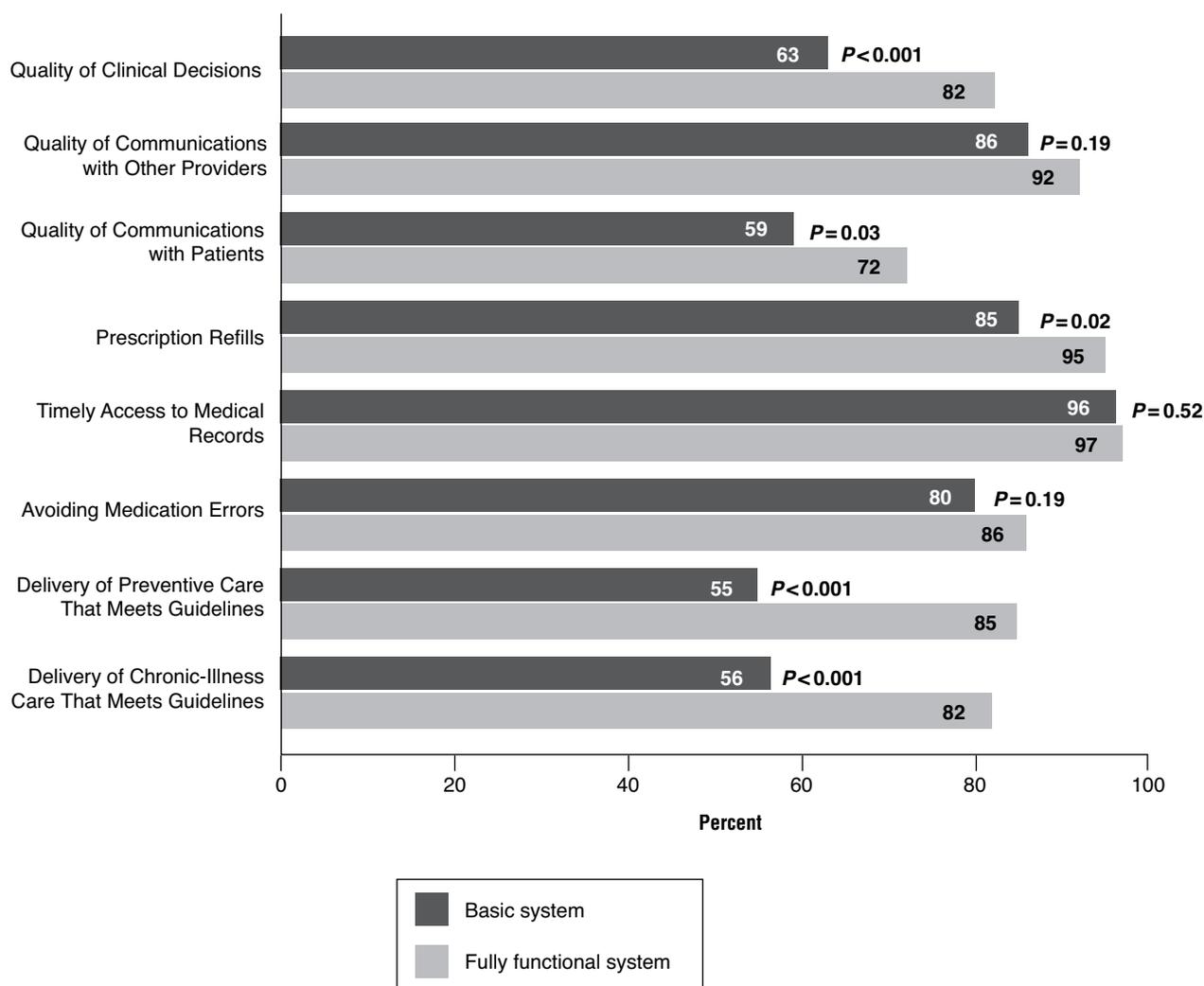
Efforts from several levels—federal, state, professional organizations, and industry—have championed increased use of HIT. One of the largest drivers is the U.S. government. CMS has initiatives designed to promote the adoption of 2 key components of HIT: e-prescribing and EHR.

E-prescribing

On July 15, 2008, Congress overrode a presidential veto and enacted the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.[20] This act makes changes to the Medicare program; in particular, a section of this act targets e-prescribing and is intended to strongly encourage its use among Part D participants. In effect, this new law provides physician incentives for e-prescribing with the intent of providing better coordinated care, improving patient outcomes, and reducing overall health care costs. Beginning in 2009, physicians who use e-prescribing for Medicare Part D recipients are eligible for an incentive payment of 2% of annual charges for Medicare services.[21] The incentive is available for a 5-year period with a decreasing incentive bonus over time. Additionally, providers who fail to use e-prescribing will be penalized beginning in 2012. The penalty increases from 1% to 2% of the annual Medicare payment by the year 2014. The law does have a safety net to exempt certain prescribers from penalties—i.e., those for whom implementing e-prescribing would be cost prohibitive (e.g., rural practitioners with limited Internet access).[21] It is hoped that the money spent on incentives will be recouped through cost savings. Over a 10-year period, Medicare has the potential to save an estimated $156 million through avoidance of adverse drug events and an additional $410 million in savings through generic medication use due to e-prescribing.[10]

The recent Medicare mandate advocating financial incentives for e-prescribing will most certainly drive increased utilization.[21] Other financial incentives may further increase e-prescribing. The Medicare Electronic Medication and Safety Protection (E-MEDS) Act of 2007 was introduced to Congress in December

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FIGURE 4 Rates of Positive Survey Responses on the Effect of Adoption of Electronic Health Record Systems[a]

Category	Basic system	P-value	Fully functional system
Quality of Clinical Decisions	63	P<0.001	82
Quality of Communications with Other Providers	86	P=0.19	92
Quality of Communications with Patients	59	P=0.03	72
Prescription Refills	85	P=0.02	95
Timely Access to Medical Records	96	P=0.52	97
Avoiding Medication Errors	80	P=0.19	86
Delivery of Preventive Care That Meets Guidelines	55	P<0.001	85
Delivery of Chronic-Illness Care That Meets Guidelines	56	P<0.001	82

Percent (0–100)

Legend:
- Basic system
- Fully functional system

[a]Used with permission from DesRoches CM, Campbell EG, Rao SR, et al. N Engl J Med. 2008;359(1):50-60.[16]

2007. If passed, this bill allows for a one-time bonus of $1,000 to $2,000 for e-prescribing to physicians who meet a threshold volume or proportion of claims for physician services for Medicare beneficiaries. To encourage adoption, the higher one-time payments ($2,000) will be provided to physicians who demonstrate early use of e-prescribing. This bill also offers ongoing incentives for the use of e-prescribing, as well as 10% reductions in reimbursement per claim if e-prescribing is not used. These reductions will be waived, however, for 1 to 2 years due to unforeseen circumstances or hardship.[22] Since its introduction, however, no additional legislative activity has occurred, and the bill remains in committee.

The push for e-prescribing extends beyond the government. Several professional organizations have launched a website (www.GetRxConnected.com) in conjunction with the Center for Improving Medication Management that supports the conversion to e-prescribing.[15,23] Through this website, prescribers can generate a report that identifies whether their EMR system is certified for e-prescribing. For those without EMR capabilities, the site provides information on the evaluation of e-prescribing technology and also offers a feature to help organizations determine the financial impact of e-prescribing. The Center for Information Management also offers consumer-directed materials that provide education about e-prescribing. To further support the adoption of e-prescribing, free software is available from the National ePrescribing Patient Safety Initiative (NEPSI), a joint project of

organizations with a goal to address the current crisis in preventable medication errors.[24]

Recognizing the many barriers faced by early adopters of e-prescribing, such as incompatible systems, companies in the private sector are working together to create solutions. One recent example of this cooperation is the merger between the e-prescribing networks of community pharmacies (SureScripts) and the largest pharmacy benefit managers (RxHub) in July 2008. This merger creates a single, secure, nationwide network for e-prescriptions that is expected to further catapult the presence of e-prescribing and increase its ease of use.[25] This joining of these 2 networks helps close the gap between community and mail-order pharmacy and will allow prescribers to access information regarding patient prescription use in both arenas. With the new network, prescribers can transmit new or renewal e-prescriptions to both community and mail-order pharmacies. This breaks down additional barriers to e-prescribing. One obstacle that remains is the prescribing of controlled substances. If e-prescribing for controlled substances becomes plausible and payers and vendors offer incentives, further e-prescribing growth can be expected. It appears that regulating the e-prescribing of controlled substances is on the horizon. The Drug Enforcement Agency (DEA) has proposed regulations that would allow e-prescribing of controlled substances as long as stringent guidelines are followed.[26] The legislation is designed to supplement existing controlled-substance regulations and would allow pharmacies to receive, dispense, and archive electronic prescriptions for Schedule II-V controlled substances. It would enable the better integration of prescription and medical records for pharmacies and hospitals.[26]

EHR

With a goal of fostering EHR implementation as a vehicle to improve quality of care, CMS recently identified participating locations for a 5-year demonstration initiative based on 2 separate incentive payments.[27] The first offers a financial reward for physician practices that adopt and use EHR and the second for reporting 26 selected quality measures beginning in the initiative's second year. Organizations who participate in this project must provide the initial financial investment. Participating practices receiving the financial incentive will need to have a Certification Commission for Healthcare Information Technology (CCHIT)-certified EHR by the end of the second year. Practices are reimbursed annually for completing an Office Systems Survey that measures the number of EHR functionalities incorporated into daily practice, with payments made for the reporting of quality measure (beginning in year 2), and performance on clinical quality measures for year 3. Over a 5-year period, the maximum per provider reimbursement is $58,000, with a maximum reimbursement of $290,000 per practice.[27]

■ Challenges to HIT Adoption

Despite the fervor surrounding potential improvements in quality of care and cost reductions, the adoption of HIT faces substantial challenges. There are individuals in every field who are slower to embrace technology. These reluctant individuals will need support in various areas to encourage adoption of HIT. Contributing factors to low adoption rates include a paucity of data supporting improved patient outcomes, privacy concerns, lack of a national standard platform for information exchange, legal concerns, and high system costs.[28]

In Massachusetts, where almost half of physicians use EHR, a random stratified survey was mailed to 1,921 physician practices in 2005.[29] One physician from each practice was chosen at random to participant in the survey, and an alternative physician was selected in the event the initially chosen physician was no longer at the practice, had retired, or was deceased. Use of an EHR was evident in fewer than 25% of practices overall; larger practices were more likely to use EHR. More than half (57%) noted physician skepticism as a barrier to adoption. Lack of computer skills, technical support, and time to learn about EHR systems were also reported by 59%, 66%, and 77%, respectively.[29]

It seems that this skepticism is not without premise. In a systematic review of published literature, Poissant et al.[30] evaluated the impact of EHRs on documentation time for physicians and nurses. For physicians, an average increase of 17.5% in documentation time was identified. Increased documentation time varied depending on the type of system, with desktop applications producing the most inefficiencies for physicians (work time increased an average of 238.4% per working shift). These authors concluded that decreased documentation time is not likely to be realized with EHR.[30] Another study conducted in dual-eligible patients of psychiatric practices found that practitioners spent an additional 45 minutes on administrative tasks for each one hour of patient care for this population.[31] Any technology that ends up increasing the administrative burden of the user, such as the increase in documentation time, will be problematic. End users will continue to be reluctant to embrace technology that pulls caregivers from their primary objective—patient care. Demonstrated benefits of HIT in decreasing administrative tasks are needed to move HIT forward.

To further complicate this problem, the incentive for physicians to invest in EHR is out of alignment in the present environment. Benefits of HIT are often noted as reductions in overall health care costs. These benefits may not be realized by providers who make the financial investment in a system. Of the estimated $77 billion that could be saved at a level of 90% EHR adoption, $23 billion would be allocated to Medicare, and $31 billion would be allocated to private payers.[11] Incentives also vary depending on the reimbursement model. In a fee-for-service model, an incentive to use an EHR would only be realized if improvements in revenue per time were improved.[32] In mixed models, the contributions of EHR to improvements in quality or performance measures may

increase the allure of adopting EHR.

A lack of widespread HIT results in an inability to achieve desired outcomes. One of the main benefits proposed for EHRs is improved coordination of care, particularly for individuals with chronic conditions or with multiple comorbidities who see multiple physicians and other ancillary services as part of their care. This benefit can only be fully realized if secure, patient-related data can move freely between providers. The low adoption rate of this technology has negated realization of this benefit in many outpatient settings.

Another problem slowing the acceptance of HIT is a lack of standards for EHR systems. Standards are needed to permit communication and interoperability between systems. There has been little incentive for businesses in the free market environment to develop standards, and purchasers of systems have not demanded this feature despite research suggesting that a savings of $78 billion could be realized with a fully integrated health care information system in the United States.[33] Returns are diminished if health information exchange is not standardized. Although the federal government has made some strides in the push for industry standards, the marketplace remains a considerable distance from adoption of functional standards.

Still, one of the major hurdles for HIT is the high cost associated with the one-time start-up and ongoing maintenance of the technology. Organizations and practice groups may agree that these systems have the potential to improve patient outcomes. Yet, skepticism about whether the initial monetary outlay will be cost beneficial remains; this is especially relevant given the state of the U.S. economy. Initial EHR costs can be prohibitive for some organizations and individual practitioners. Cost estimates for implementing an EHR system in the ambulatory setting must include the start-up outlay for hardware, software, and licensing, as well as costs related to the process of implementation (e.g., training, temporary loss of productivity).[6] Per physician start-up costs have been reported to vary between $15,000 and $50,000; benefits such as decreased staffing costs and increased revenue may not be realized and are dependent on the specific EHR system.[34] Physicians have cited initial technology costs as a major barrier to adoption of EHRs.[16] Return on investment (ROI) remains a sticking point for many providers. In a recent national survey, 50% of physicians who had not adopted EHR technology cited uncertainty of achieving an ROI as a barrier to adoption.[16]

In a review of 14 solo and small physician group practices, EHR costs (one-time and ongoing costs for hardware, software, information systems staffing, external contractor services, installation, training, abstraction, productivity loss, and telecommunications) and EHR benefits (decreases in compensation for medical records and other support staff, decreases in transcription and paper supply costs, increased visits due to reduced provider time per visit, decreased provider time at work, and revenue enhancement from higher payment for increased levels of coding for visits) were calculated to determine the time to achieve an ROI.[12] The average time to pay for EHR was 2.5 years with a profit realized soon after. However, it would take 1 practice 9 years to see a positive ROI, and 2 practices would never realize a positive return.

Current initiatives by public and private sectors to improve adoption of HIT through providing either up-front support in the form of software and hardware or monetary incentives for using the technology coupled with results from the literature on positive ROI for physicians who adopt HIT will help to increase its acceptance and use.

HIT: What Will the Future Bring?

The low current adoption rate appears to make attainment of the 2014 goal an improbable task, yet there are positive signs that acceptance may be increasing. The emphasis placed on increasing HIT adoption through CMS initiatives should attract the attention of physicians. If initiatives such as demonstration projects support improved quality and lower costs, leaders in the health care industry can use this to encourage further adoption of HIT.

CMS and the Office of the Inspector General have also created rules in response to concerns about how existing regulations may impact the adoption of HIT.[35] The intention is to remove barriers that prohibit the transfer of software and systems hardware to enable provider collaboration to develop effective HIT systems. While the e-prescribing rules are more stringent than EHR regulations, the new provisions allow for donations of technology under certain conditions. Any EHR software donation must include an e-prescribing capability that is compliant with the Medicare Drug Benefit Standards. The new rules require a written agreement outlining the terms of the donation, and recipients are required to pay 15% of the donation's cost.

■ Conclusion

It is believed that through public and private incentives for using HIT, the adoption rate of this technology will increase. It is only through increased adoption that the potential benefits, such as improved care coordination, will be realized. Studies must continue to provide data to support improvements in quality of care and cost reductions that accompany HIT adoption. Recognizing the barriers to HIT adoption and creating systems to address these barriers will also be critical to promote increased use. While this may seem to be an unachievable goal today, the adoption and use of EHR continues to slowly grow. This pace could potentially accelerate with continued support and ongoing initiatives from the government, medical organizations, and industry.

REFERENCES

1. Schoen C, Osborn R, Huynh P, Doty M. The Commonwealth Fund 2006 International Health Policy Survey of Primary Care Physicians in Seven Countries. Available at: www.commonwealthfund.org/usr_doc/Schoen_200 6intlsurveyprimarycareMDs_chartpack.pdf?section=4039. Accessed October 8, 2008.

2. The White House. Transforming health care: the President's health information technology plan. Available at: www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html. Accessed September 21, 2008.

3. Massachusetts Health Data Consortium. Benefits of ePrescribing. Available at: www.mahealthdata.org/ma-share/projects/e-prescribinged/20060627_eRxBenefitsFactSheet.pdf. Accessed October 9, 2008.

4. Centers for Medicare & Medicaid Services. E-prescribing. Overview. Available at: www.cms.hhs.gov/EPrescribing/. Accessed September 9, 2008.

5. Institute of Medicine. Committee on Data Standards for Patient Safety. *Key Capabilities of an Electronic Health Record System: Letter Report.* Washington, DC: National Academies Press; 2003.

6. Shekelle PG, Morton SC, Keeler EB. Costs and Benefits of Health Information Technology. Evidence Report/Technology Assessment No. 132. (Prepared by the Southern California Evidence-based Practice Center Under Contract No. 290-02-0003.) AHRQ Publication No. 06-E006. Rockville, MD: Agency for Healthcare Research and Quality. April 2006.

7. Asch S, McGlynn E, Hogan M, et al. Comparison of quality of care for patients in the Veterans Health Administration and patients in a national sample. *Ann Intern Med.* 2004;141(12):938-45.

8. Chaudhry B, Wang J, Wu S, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. *Ann Intern Med.* 2006;144:742-52. Available at: www.annals.org/cgi/reprint/144/10/742.pdf. Accessed December 18, 2008.

9. eHealth Initiative. eHealth initiative releases results from 2008 survey on Health Information Exchange. Summary of key findings. Available at: www.ehealthinitiative.org/HIESurvey. Accessed September 23, 2008.

10. Centers for Medicare & Medicaid Services. 42 CFR Part 423. *Fed Regist.*73(67):18918-42.

11. Hillestad R, Bigelow J, Bower A, et al. Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. *Health Aff (Millwood).* 2005;24(4):1103-17.

12. Miller R, West C, Brown T, Sim I, Ganchoff C. The value of electronic health records in solo or small group practices. *Health Aff (Millwood).* 2005;24(5):1127-37.

13. Wang S, Middleton B, Prosser L, et al. A cost-benefit analysis of electronic medical records in primary care. *Am J Med.* 2003;114:397-403.

14. Evans D, Nichol W, Perlin J. Effect of the implementation of an enterprise-wide electronic health record on productivity in the Veterans Health Administration. *Health Econ Policy Law.* 2006;1(Pt. 2):163-69.

15. SureScripts. National progress report on e-prescribing. December 2007. Available at. www.surescripts.com/pdf/National-Progress-Report-on-EPrescribing-1.pdf. Accessed September 8, 2008.

16. DesRoches CM, Campbell EG, Rao SR, et al. Electronic health records in ambulatory care—a national survey of physicians. *N Engl J Med.* 2008;359(1):50-60.

17. National Coalition on Health Care. Facts on Health Care Costs. Available at: www.nchc.org/documents/cost_fact_sheet_2008.pdf. Accessed December 18, 2008.

18. Institute of Medicine. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 2000.

19. Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Quality Chasm Series. *Preventing Medication Errors* (Executive Summary). Washington, DC: National Academies Press; 2007.

20. GovTrack.us. H.R. 6331: Medicare Improvements for Patients and Providers Act of 2008. Available at. www.govtrack.us/congress/bill.xpd?bill=h110-6331. Accessed September 9, 2008.

21. Glendinning D. American Medical Association, E-prescribers see Medicare bonus, but late adopters will face pay cut. AMedNews.com. Available at: www.ama-assn.org/amednews/2008/08/04/gvl10804.htm. Accessed September 9, 2008.

22. eHealth Initiative. Medicare Electronic Medication and Safety Protection (E-MEDS) Act of 2007. Available at: www.ehealthinitiative.org/assets/documents/eHealth%20Initiative%20Summary%20of%20the%20EMEDS%20 Bill%20Feb-2008.pdf. Accessed September 18, 2008.

23. The Center for Improving Medication Management. Programs & Research. Available at: www.thecimm.org/programs.htm. Accessed October 10, 2008.

24. National ePrescribing Patient Safety Initiative (NEPSI). Free electronic prescribing...for every physician in America. Available at: www.nationalerx.com/?gclid=CJrLyuevmpYCFR-uQAodCnKs7A. Accessed October 9, 2008.

25. SureScripts. SureScripts-RxHub announce merger. Available at: www.surescriptsrxhub.com/. Accessed September 10, 2008.

26. US Department of Justice. Drug Enforcement Administration. Office of Diversion Control. Rules-2008. Available at:. www.deadiversion.usdoj.gov/fed_regs/rules/2008/fr0627.htm. Accessed December 4, 2008.

27. Centers for Medicare & Medicaid Services. Electronic health records (EHR) demonstration. Demonstration summary. Available at: www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/EHR_DemoSummary.pdf. Accessed September 21, 2008.

28. Burton L, Anderson G, Kues I. Using electronic health records to help coordinate care. *Milbank Q.* 2004;82(3):457-81.

29. Simon S, Kaushal R, Cleary P, et al. Correlates of electronic health record adoption in office practices: a statewide survey. *J Am Med Inform Assoc.* 2007;14(1):110-17.

30. Poissant L, Pereira J, Tamblyn R, Kawasumi Y. The impact of electronic health records on time efficiency of physicians and nurses: a systematic review. *J Am Med Inform Assoc.* 2005;12(5):505-16.

31. Wilk JE, West JC, Rae DS, Rubio-Stipec M, Chen J, Regier D. Medicare Part D prescription drug benefits and administrative burden in the care of dually eligible psychiatric patients. *Psychiatr Serv.* 2008;59(1):34-39.

32. Middleton B, Hammond W, Brennan P, Cooper G. Accelerating U.S. EHR adoption: how to get there from here. recommendations based on the 2004 ACMI retreat. *J Am Med Inform Assoc.* 2005;12(1):13-19.

33. Walker J, Pan E, Johnston D, Adler-Milstein J, Bates D, Middleton B. The value of health care information exchange and interoperability. *Health Aff (Millwood).* 2005; (Suppl) Web Exclusives:W5-10-W15-18.

34. California HealthCare Foundation. Electronic medical records: lessons learned from small physician practices. Available at: www.chcf.org/documents/healthit/EMRLessonsSmallPhysicianPractices.pdf. Accessed September 20, 2008.

35. Center for Medicare & Medicaid Services. Physician self-referral exceptions for electronic prescribing and electronic health records technology. Available at: www.cms.hhs.gov/apps/media/press/release.asp?Counter=1920. Accessed November 25, 2008.

The Future of Medicare Part D Drug Plans—
Results From a Roundtable Discussion

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ABSTRACT

BACKGROUND: The Medicare Prescription Drug, Improvement, and Modernization Act, signed into law in 2003, provided access to prescription drugs for elderly Americans. The Part D benefit continues to evolve. Changes in plan designs, the impact of the doughnut hole on beneficiaries, and increased cost shifting have the potential to hamper the future of the Part D benefit.

OBJECTIVE: To discuss factors that will likely have the most impact on the future of Medicare Part D from a patient and payer perspective.

SUMMARY: The continued growth of the elderly population is expected to place an increasing burden on the services provided through Medicare. Given the current financial situation, it has been predicted that Medicare's Hospital Insurance Trust Fund will be depleted by 2019. To provide quality benefits and remain competitive, health plans are continually evaluating and redesigning their Part D benefits. However, the current regulatory environment is preventing plans from offering innovative products and designs that could lower costs to beneficiaries. The growing number of beneficiaries hitting the doughnut hole is also becoming a concern for both beneficiaries and health plans. More beneficiaries are reaching the doughnut hole, and this has resulted in changes in beneficiary behaviors, including stopping medications, switching to alternative drug classes, and reducing medication use. Because of the increasing concerns about Medicare's sustainability, it is anticipated that the government may become more involved.

CONCLUSION: As the health care landscape continues to change, payers will be challenged to offer benefit designs that are affordable to elderly beneficiaries. For its part, the government must allow plans to design benefits that will improve the overall quality of care. Additionally, closer attention must be given to the growing number of beneficiaries hitting the doughnut hole and its potential adverse clinical and economic consequences.

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The intent of Medicare Part D was to provide all elderly Americans with access to prescription medication. Despite its relative infancy, questions about the future of Medicare Part D are already being raised. The number of qualified elderly is increasing, and concerns about the added economic drain of this newer benefit on the already inadequately funded general Medicare benefit are increasingly heard. Plans are restructuring to adjust to changes in regulations and market pressures, often resulting in cost-shifting to the beneficiary. Furthermore, although Part D was designed to allow the private sector to administer the benefit, there is growing pressure for increased government involvement in the process.

Economic Forecast Is Dismal

The sustainability of Medicare from a financial standpoint has been the source of much debate. The increasing U.S. elderly population is expected to add financial strain to an already stretched system.[1] Census Bureau data indicate that the United States is on the cusp of an elderly population explosion because of aging Baby Boomers.[2] By 2030, the population of people aged ≥65 years is expected to be twice as large as it was in the year 2000 (72 million vs. 35 million). Taking this projected increase into account, roughly 1 in 5 Americans will be elderly by 2030 (Figure 1).

Medicare costs in 2007 accounted for 3.2% of the gross domestic product (GDP). The ratio of Medicare costs to the GDP is expected to rise sharply over the coming years and surpass the costs of Social Security by 2028 (Figure 2).[3]

According to the 2008 Social Security and Medicare Trustees reports, current financing arrangements are not sufficient to maintain the programs over the long term.[3] The impending financial difficulty for Medicare will be realized before that of Social Security—Medicare's Hospital Insurance (HI) Trust Fund will be depleted by 2019, followed by Social Security reserves in 2041. The HI Trust Fund pays for inpatient hospital and related care; the Medicare Supplementary Medical Insurance (SMI) Trust Fund pays for prescription benefits under Medicare Part D, and a separate part of this trust pays for physician and outpatient services. Social Security is funded by two additional trusts, Old-Age and Survivors Insurance (OASI) and Disability Insurance (DI). These trusts are funded through taxes, premiums, and other dedicated revenues.

However, escalating health care costs require additional financing of these funds through general fund revenue because incomes from stagnate wages cannot keep pace with rising health care expenditures.[3] It is anticipated that general revenue transfers to Medicare to help fund the program will account for

Older Americans Will Comprise 20% of the Total Population By 2030[a]

Percent Aged 65 and Over of the Total Population: 2000 to 2050
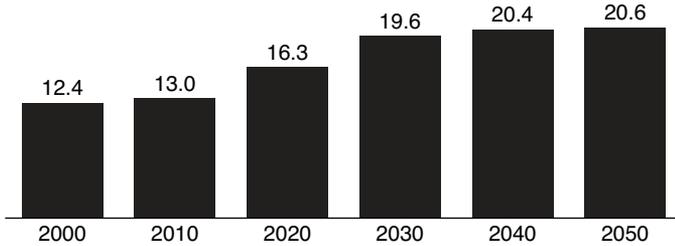
[a]Excerpted from He W, Sengupta M, Velkoff V, DeBarros K. U.S. Census Bureau, Current population reports (2005).[2]

Note: The reference population for these data is the resident population.

FIGURE 2 Projected Costs of Medicare Will Surpass Social Security by 2028[a]

Social Security and Medicare Cost as a Percentage of GDP

[a]Excerpted from: A Summary of the 2008 Annual Reports: Social Security and Medicare Board of Trustees.[3]

DI = Disability insurance; GDP = gross domestic product; HI = Hospital Insurance Trust Fund; OASI = Old-Age and Survivors Insurance; SMI = Supplementary Medical Insurance.

approximately half (45%) of Medicare's outlays by 2014—this has helped fuel the current Medicare funding warning.[3] This warning, signaling an inadequacy in the trust fund's dedicated financing, requires action from the President and Congress to examine the impact of Medicare on the federal budget in an expedited fashion.

The outlook for Part D financing is not quite as bleak as that for Medicare as a whole, since financing for the next year is automatically provided by law and is based on projected costs for the subsequent year.[3] Federal general fund revenues are used to pay for 75% of Part D expenditures and the remaining costs are covered by the beneficiaries' monthly premium charges.[3] Rapidly rising costs, however, are expected to affect Part D as well. These costs will be offset through increased cost shifting to the beneficiary—costs to beneficiaries are expected to grow and exceed the growth of both the economy and beneficiary incomes.[3] This cost shifting will force the individual to assume more financial responsibility for prescription drug costs.[4]

Evolution of Medicare Part D Plans

Medicare Part D plan administrators will need to continually evaluate plan structure and reconfigure plan design to meet the challenges of increased costs and remain competitive. According to Summit participants, the current regulatory environment and Centers for Medicare and Medicaid (CMS) oversight of Part D programs has created some frustrations among plan sponsors and has limited the ability to offer innovative products and solutions.

Since the introduction of Medicare Part D in 2006, the prescription drug plan benefit has been available as either stand-alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. Plans must meet minimum requirements, and offerings vary based on benefit design, cost, gap coverage, formulary, and utilization management rules. The 2008 standard benefit includes a $275 annual deductible, 25%
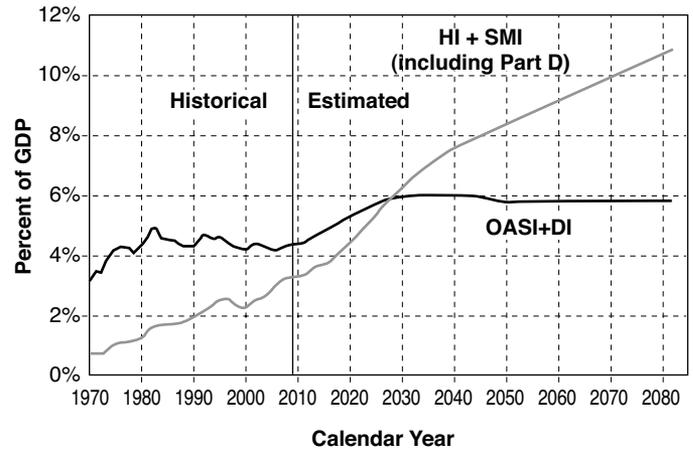
coinsurance up to an initial benefit threshold of $2,510 in total drug costs, and a coverage gap where the beneficiary pays 100% for the next $3,216 in drug costs (the so-called doughnut hole). The catastrophic coverage threshold is met at $5,726 in total costs ($4,050 in out-of-pocket spending), with the beneficiary paying 5% co-insurance, the plan assuming 15%, and Medicare bearing 80% of all further costs for the remainder of the calendar year.[5] Currently, more than 25 million Medicare recipients are enrolled in Part D plans, with 70% in a stand-alone PDP and 30% in an MA-PD plan.[6] The number of stand-alone PDPs increased from 2006 to 2007 but remained relatively stable in 2008. There has been some speculation that PDPs will phase out over time and are simply a transition product until beneficiaries convert to MA-PD plans.[7] The authors concur with this assessment and predict the number of stand-alone PDPs will continue to decrease in the coming years.

Monthly premiums for drug plans differ based on the benefits offered. In general, premiums have increased each year and are in line with increased drugs costs.[8] The average monthly premiums for PDPs in 2009 are expected to be approximately $28 and about $17 for MA-PD plans. These figures are actually lower than what was originally projected for 2009.[8] Plans that offer some gap coverage tend to having higher monthly premiums.[6] Plans offering the standard benefit often encourage generic drug use and less expensive therapeutic alternatives to keep beneficiaries from reaching the coverage gap.

Cost sharing has increased since the introduction of Medicare

Part D, with many PDPs using tiered copayments; the amount of these copayments varies significantly between plans and is typically much lower for participants in larger, national PDPs. Currently, most PDPs also target high-cost medications and place them on a specialty tier as a cost-containment strategy.[6] The number of plans implementing a specialty tier doubled from 2006 to 2008.[6] With the emphasis on generic medication use, plans offer greater coverage for generic medications and shift the cost of branded and specialty medications to the beneficiary. Formulary and utilization management tools are increasingly used to manage drug costs and, depending on the benefit design, may increase the number of participants affected by the doughnut hole. Even with an open formulary, utilization management may restrict access to formulary drugs through step therapy, quantity limits, or prior authorization.[6]

Growing Burden of the Doughnut Hole

The doughnut hole, or gap in coverage, is a feature of Part D that increases the financial burden for many beneficiaries. The gap occurs when enrollees meet a set level of drug spending ($2,510 in 2008) and remains in place until a designated out-of-pocket spend has occurred (e.g., in 2008, beneficiaries are responsible for $3,216 while in the gap).[5,6] For 2008, this translated to $5,726 in total drug spending before catastrophic benefits are in place. The value of the coverage gap is expected to double between 2007 and 2017, placing a significant financial burden on enrollees.[9] A low-income subsidy (LIS) is available to assist beneficiaries who qualify; these individuals are not required to pay for medications in the coverage gap.[9] In 2007, 26% of non-LIS Part D enrollees reached the coverage gap. For those non-LIS beneficiaries with limited funds, the out-of-pocket expenses may hinder medication compliance. Documented changes in drug use for a representative sample of beneficiaries have occurred when enrollees reach the coverage gap (Figure 3). These changes include stopping medications, switching to an alternative drug class, and reducing medication use.[9] As Part D plans continue to mature, careful attention to the doughnut hole's impact must be monitored to determine if the care of patients with serious chronic medical conditions is compromised.

### Potential for Increased Government Involvement

While Part D has successfully increased medication access for millions of Americans, questions about cost continue to surface, and strategies to reduce and/or contain these costs remain at the forefront of Part D discussions. One of the biggest unanswered questions is whether negotiation of drug prices should remain in the private sector or move under government influence.[10] While the government leveraged its purchasing power to obtain lower drug prices, price negotiation for Part D plans was left up to private plans because it was believed that market competition among plans would result in lower overall drug prices.

A report issued by the U.S. House of Representatives Committee

| FIGURE 3 | Medication Drug Use Changes for Representative Medication Classes— Doughnut Hole[a] |

Changes in Drug Use By Part D Enrollees Who Reached the Coverage Gap in 2007

Among Part D enrollees who reached the coverage gap, percent who:
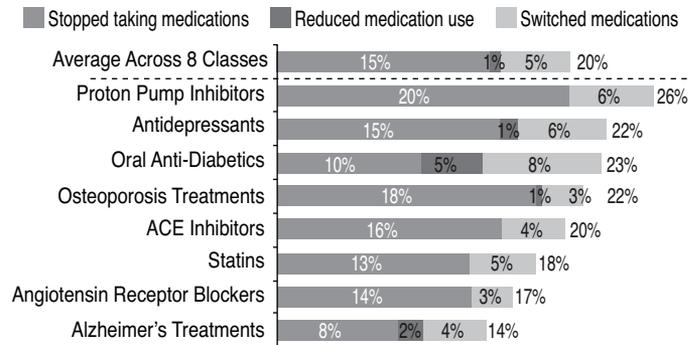
[a]Excerpted from "The Medicare Part D Coverage Gap: Costs and Consequences in 2007. The Henry J. Kaiser Family Foundation, August 2008.[9] This information was reprinted with permission from the Henry J. Kaiser Family Foundation. The Kaiser Family Foundation is a non-profit private operating foundation, based in Menlo Park, California, dedicated to producing and communicating the best possible information, research, and analysis on health issues.

on Oversight and Government Reform in July 2008 addressed Medicare Part D pricing. Coverage for "dual eligibles"—elderly and disabled individuals qualifying for both Medicare and Medicaid—was a focus of the report, since Medicare Part D provides coverage for approximately 6 million dual eligible beneficiaries who, prior to the Part D rollout, received medications from Medicaid. These individuals account for at least 50% of drug spending through Part D and generally have lower incomes; 98% of their drugs costs are covered by taxpayers through Part D.

Based on a review of confidential data from Part D's 10 largest insurers and Medicaid pricing from drug manufacturers, the committee found that prices paid for 97 of the top 100 prescription drugs used by dual beneficiaries were higher than prices paid for Medicaid.[11] The prices for essential medications as defined by the CMS-protected list were especially high—rebates and discounts of only 7% were available to Part D insurers for 16 of the protected list drugs appearing on the top 100 list. Compared to Medicaid pricing for these same medications, the cost was 40% higher for Part D insurers. In its report, the committee noted that for the years 2006-2007, drug discounts offered by Medicare Part D were $3.7 billion less than those offered by Medicaid ($2.6 billion vs. $6.3 billion, respectively).[11] This difference results from rebates that Medicaid had negotiated with manufacturers. The report concludes that a savings for dual eligibles of $86 billion over the next 10 years could be realized if Part D insurers were

given price discounts equal to those of Medicaid.[11]

As discussed in the section, "Current Management of Part D Benefits," (see page S4) CMS regulations regarding formulary coverage may have impeded the ability of the plans to negotiate the level of cost savings traditionally secured for commercially covered lives. Furthermore, while the potential for cost savings that could be realized from government-led Medicare price negotiations may be enticing, there is no guarantee that this level of savings will actually come to fruition. In a recent congressional report, the potential implications of federal price negotiations were reviewed.[12] Concerns about centralized negotiations include the restriction of formulary choice; for example the number of drugs in the Veterans' Affairs formulary is considered much more restrictive than the formularies in private plans. The effect of government pricing on pharmaceutical manufacturers and their ability to continue funding research and development has also been raised. Negotiated prices that are passed to plans may decrease the ability of plans to remain competitive, resulting in a reduced number of available plans. Another consequence of set drug prices for the Medicare population would be the effect of this pricing on other markets—especially the pricing of medications for non-Medicare recipients. There is a possibility that Medicare beneficiaries will bear the brunt of federal negotiations as higher costs are passed to these individuals.

Strong arguments against government influence have been put forth by the Academy of Managed Care Pharmacy (AMCP).[13-15] AMCP opposes government interference and supports a competitive model for the provision of Medicare Part D benefits. AMCP raises concerns about the separation of formulary development and pricing. In its official position on this issue, AMCP states, "Authorizing the federal government to negotiate the purchase price of drugs under the Medicare Part D program would inappropriately separate price negotiation from the formulary development process."[14] AMCP further states, "Mandatory requirements imposed by the government could weaken the program, disadvantage beneficiaries, and threaten the long term financial success of the benefit."[15]

◼ Conclusion

Medicare Part D will continue to evolve as the landscape of health care changes. If Medicare is going to remain a viable health benefit in the United States, funding issues need to be addressed, and a solution that prevents the exhaustion of the trust funds must be enacted. The structure of the plans will also continue to evolve. It is too early in the Part D story to determine how the drug plan benefit will play out and whether PDPs will phase out or if the number of plans will diminish in response to increased regulation and oversight. If the coverage gap remains an active concern and cost shifting to the patient continues, the effect of the increasing economic burden on beneficiaries will require a closer look. Greater government involvement in the negotiation of drug pricing may be on the horizon.

REFERENCES

1. Henry J. Kaiser Family Foundation. Medicare: a primer. March 2007. Available at: www.kff.org/medicare/upload/7615.pdf. Accessed December 18, 2008.

2. He W, Sengupta M, Velkoff V, DeBarros K. U.S. Census Bureau, Current population reports, P23-209, 65+ in the United States: 2005. Washington, DC: U.S. Government Printing Office; 2005.

3. Social Security Administration. A Summary of the 2008 Annual Reports: Social Security and Medicare Board of Trustees. Available at: www.ssa.gov/OACT/TRSUM/trsummary.html. Accessed September 22, 2008.

4. National Coalition on Health Care. Facts on Health Care Costs. www.nchc.org/documents/cost_fact_sheet_2008.pdf. Accessed December 18, 2008.

5. Hoadley J, Hargrave E, Merrell K, Cubanski J, Neuman T. Medicare Part D 2008 data spotlight: benefit design. Henry J. Kaiser Family Foundation. Available at: www.kff.org/medicare/upload/7713.pdf. Accessed September 22, 2008.

6. Hoadley J, Hargrave E, Cubanski J, Neuman T. Medicare prescription drug plans in 2008 and key changes since 2006: summary of findings. Henry J. Kaiser Family Foundation. Available at: www.kff.org/medicare/upload/7762.pdf. Accessed September 22, 2008.

7. Carroll J. Managed Medicare revitalized: feel-good plan of the decade. *Manag Care.* 2006;15(9):22-24, 26-28, 33. Available at: www.managedcaremag.com/archives/0609/0609.medicare.html. Accessed December 18, 2008.

8. Centers for Medicare & Medicaid Services. Press Releases. Lower Medicare Part D costs than expected in 2009. Available at: www.cms.hhs.gov/apps/media/press/release.asp?Counter=3240&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date. Accessed September 22, 2008.

9. Hoadley J, Hargrave E, Cubanski J, Neuman T. The Medicare Part D coverage gap: Costs and consequences in 2007. Henry J. Kaiser Family Foundation. Available at: www.kff.org/medicare/upload/7811.pdf. Accessed September 22, 2008.

10. Frank R, Newhouse J. Should drug prices be negotiated under Part D of Medicare? And if so, how? *Health Aff (Millwood).* 2008;27(1):33-43.

11. United States House of Representatives. Committee on Oversight and Government Reform Majority Staff. Medicare Part D: pricing and manufacturer windfalls. Available at: www.oversight.house.gov/documents/20080724101850.pdf. Accessed September 23, 2008.

12. Hahn J. CRS Report for Congress. Federal drug price negotiation: implications for Medicare Part D. Available at: www.policyarchive.org/bitstream/handle/10207/3053/RL33782_20070105.pdf?sequence=1. Accessed October 9, 2008.

13. Academy of Managed Care Pharmacy. Future of Medicare Part D: Competitive Model. http://69.0.204.76/amcp.ark?p=AA5B4A21. Accessed September 23, 2008.

14. Academy of Managed Care Pharmacy. Future of Medicare Part D: Reliance on Medicare Part D plan sponsors to negotiate prices with pharmaceutical manufacturers. Available at: http://69.0.204.76/amcp.ark?p=AA5B4A21. Accessed September 23, 2008.

15. Academy of Managed Care Pharmacy. Future of Medicare Part D: Formularies offered by Part D insurance plans provide patients with access to effective, safe, and affordable medications. Available at: http://69.0.204.76/amcp.ark?p=AA5B4A21. Accessed September 23, 2008.

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