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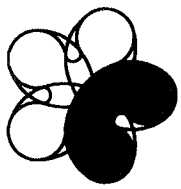

National Kidney Foundation™

December 14, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

The National Kidney Foundation (NKF) is pleased to respond to the Proposed Rule, Medicare Program; Medicare Part D Data, published in the Federal Register on October 18, 2006 [CMS-4119-P], on behalf of its 50,000 members, who include kidney patients, the health care professionals who serve their needs, and concerned members of the lay public nationwide. We believe that the Secretary should have the authority to use Part D claims information for research, analysis, reporting, and public health functions, and, therefore, support the Proposed Rule.

Information to be Collected

Americans with chronic kidney disease (CKD) are not well represented in the populations studied in clinical trials as demonstrated by a recent analysis showing 56 % of randomized controlled trials in cardiovascular disease exclude kidney disease patients. (Please see S.G. Coca, et al. Underrepresentation of Renal Disease in Randomized Controlled Trials of Cardiovascular Disease, Journal of the American Medical Association, September 20, 2006). This has led to severe limitation in our knowledge of the therapeutic effects and complications that occur in kidney disease patients. Access to Part D data to investigators is critical to advancing the public health surveillance data to better understand how well specific drugs work for CKD patients. There are many additional potential uses of Part D data that could facilitate improved quality of care and quality of life for kidney patients. For example, while CKD affects an estimated 20 million Americans, not all of them will ultimately experience kidney failure (ESRD), requiring dialysis or a kidney transplant covered by the Medicare ESRD Program, since this is the minority event in this population compared to the larger issues related to cardiovascular disease morbidity and mortality. Access to Part D data could shed light on the impact of Angiotensin Converting Enzyme Inhibitors/Angiotensin

Receptor Blockers, and other drug interventions, on the progression of CKD to kidney failure. The individual level data on prescription drug utilization will also help determine if active treatment is occurring for the major morbidity from cardiovascular disease. This is particularly true for minority populations, and other subgroups of the U. S. population, for whom the burden of kidney disease is disproportionately high. The analysis made possible by access to Part D data could, in turn, help to alleviate demands on the Medicare ESRD program.

Lastly, the kidney transplant population is an important subgroup to assess treatment of effectiveness of immunosuppressive drugs to prevent transplant rejection but also to assess treatment of complications. The second leading cause of kidney graft failure is death from cardiovascular disease, which has received relatively little attention compared to graft rejection. The care of the transplant patient in the post transplant period is extremely important, so much so that our own Board of Directors have committed $1 million dollars to develop a clinical set of guidelines for kidney transplant patients. Central to that effort is access to drug treatment of cardiovascular disease as well as post transplantation diabetes.

Information to be Collected: Data Sharing With Entities Outside of CMS

It is stated in the Proposed Rule that CMS should be able to share data from the Medicare Prescription Drug Program with the FDA and AHRQ. We suggest that CMS should also be able to share data with the National Institutes of Health, in particular, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and with individuals and entities conducting NIDDK-supported research, such as the United States Renal Data System. The USRDS and the recent CDC surveillance systems for the CKD population will need critical access to treatment data to determine assess to care and effectiveness of interventions. The merging of the Part D prescription data with the Medicare administrative data allow the public health sector to determine the implications of recommended care as actual access to care. This is particularly true for the populations with a heavy burden of kidney disease.

Beneficiary Access to Part D Data

We support this important proposal that could contribute to patient care in several ways. Patients would have a clear and accurate list of medications to present to health care providers for routine outpatient and emergency services. Patients with CKD often require multiple medications and are not always able to identify them accurately, making this proposal particularly useful. Beneficiary access to the data should also contribute to patient education about the importance of adherence to medications, including utilization review to provide feedback regarding appropriate refill practices consistent with prescribing instructions. The impact of beneficiary access to drug data on patient outcomes is also attractive for clinical research purposes.

The Proposed Rule calls for a data sharing agreement that would protect confidentiality of beneficiary information. The data sharing principles should address the patient protections in Privacy Act of 1974, 5 USCA section 552a. There should be specific oversight of merged data requests by the government of ensure the data is used in the best interest of the patients and the public health and welfare.

Thank you for your attention to these comments.

Sincerely,

Allan J. Collins

Allan J. Collins, MD
President
National Kidney Foundation, Inc.

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

December 18, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4119-P
POB 8017
Baltimore, MD 21244-20580

Re: Support of CMS's Effort to Make Part D Data Available for Research

Pharmacists Planning Service, Inc. (PPSI), a 501 C (3) nonprofit public health, consumer, pharmacy education organization, strongly supports CMS's effort to make the Medicare Modernization Act (MMA) Part D data available for research and for transparency in order to better understand and improve the MMA program.

PPSI submits the following reasons for making prescription drugs on Medicare data for evaluation and research as follows:

1. At the American Public Health Association (APHA) annual meeting held in Boston in November, 2006, PPSI put on a Medicare Part D Workshop (see pp 1)

2. One of the most glaring problems of the MMA program is the failure to have uniform standards for pharmacy practice with no transparency (see pp 2).

3. Pharmacy practice for measuring quality and access to pharmacy services was adopted January 24, 1997 by CMS with no data or transparency (see pp 3-4).

4. Since the MMA has been privatized with no standards we see Medco, one of the largest PBMs and one of the big fours, paying a $155 million dollar fine to settle fraud/kick-back charges, illegal switching of drugs. CMS needs transparency. This could be avoided if there was data coming out of the PBMs/PDPs. (see pp 5-6).

5. PPSI sees illegal activity of PBMs withholding information (see pp 7-10).

6. The number one problem that needs to be solved immediately is the lack of data and transparency which is not required under MMA. WE ARE TRYING TO FIX THIS LACK OF TRANSPARENCY WITH THE ENCLOSED FEDERAL REGISTRY TO SUPPORT CMS' EFFORTS TO MAKE PART D DATA AVAILABLE FOR RESEARCH.

7. Failure to have access to the information data and transparency issues results in increased fraud and abuse by the PBMs/PDPs/HMOs.

8. Example: Dr. David Graham said five widely used drugs are called unsafe and should be off the market. (Dr. Graham spoke at the APHA annual meeting. (P.11).

9. These listed drugs are Accutane, Bextra (now off the market), Crestor, Meridia, and Serevent. Since most of the PBMs/PDPs, as you can see from the litigation, make their money from rebates/kick-backs and formularies, Crestor has now been put on many of the MMA formularies even though Dr. Graham said that it results in muscle-destroying side

effects, Rhabdomylosis, and acute renal and kidney failure. One of top four, CCRx/PBM, now has Crestor as preferred brand. (pp 12)

10. What is needed is evidence-based medicine (EBM) similar to what they have in Oregon and also what we used to have under the old Medi-Cal drug formulary, a P & T or formulary committee with some oversight of CMS (see pp 13-14).

11. Finally, MMA must have a simple process method in order to get "medically needed" prescription drugs in a timely manner similar to the old Medi-Cal "treatment authorization request (TAR)" which is not available. This would become available with evaluation and research data from the PDPs/PBMs/HMOs.

In conclusion, we need to do the following:

1. Adopt standards of practice for the pharmacy profession that has already been done. This can be accomplished with available data.

2. Give CMS some congressional power for oversight which is presently not available by increasing the collection of Part D Medicare drug data.

3. Adopt some measures to get transparencies over the PBM/PDP industry.

4. Get evidence-based medicine (EBM) as soon as possible through data.

5. Get some "teeth" into the FDA so that they can control the industry.

6. Pharmacy has gone from 2 billion to 3 billion Rx's per year to now 4 billion in 2007. We need to fix the 30 day supply system so that all pharmacies are allowed to give 90 day maintenance drugs. This will reduce Rx's by 50% allowing pharmacists to consult and save consumers/patients' money on co-pays. This will be demonstrated through data collection, research & evaluation of formularies.

7. Because of the lack of transparency under the Medicare Part D program, the risk from popular medications and bad drug reactions which send 700,000 to emergency rooms yearly will only increase because of the switching of prescription drugs for profit vs. the evidenced-based medicine along with the mandatory thirty day supply in many pharmacies vs. the ninety day supply in the mailorder pharmacies owned by the PBM/PDP/HMO/MCO's. This will definitely decrease with data. (see pp 20)

8. By decreasing the number of prescriptions by allowing a ninety day supply, pharmacists will be allowed to counsel and check for adverse drug reactions on computer screens which currently cannot be done according to the NACDS's white paper where 73% of pharmacy time is being spent on non-pharmacy related issues. (P 21).

PPSI strongly recommends support for CMS to make Part D's (Medicare Drugs) data available for research in all PDP/PBM/HMO/MCO's health plans.

Thank you for the opportunity to respond.

Fred S. Mayer, R.Ph., M.P.H.
President, PPSI

American Public Health Association

APHA Scientific Session
Business Meeting

245.0: Sunday, November 5, 3006
2 p.m. - 5 p.m.
Boston Convention Center, Room 216
Boston, Massachusetts

MEDICARE PART D WORKSHOP

Moderator
Fred S. Mayer, R.Ph., M.P.H.
President, PPSI
Past President, California Public Health Association (CPHA)

"An Update from CMS"
Adele Pietrantoni, Pharm.D.
Centers for Medicare & Medicaid Services, (CMS) Region I

"Medicare Part D: Poor Public Policy To Begin With, Or Just Mishaps
In Implementation Of The New Drug Benefit: Toward Assessing What Can Be Done Better"
J. Warren Salmon, Ph.D., Professor of Pharmacy and Public Health
University of Illinois, Chicago, Illinois

"Outreach and Education to Vulnerable Populations
Under Medicare Part D"
Meghana Desai, B.Pharm., MBA, Ph.D. Doctoral Student
University of Illinois, Chicago, Illinois

"Simple Steps to Prescription Drug Reform"
Alan Sager, Ph.D. and Deborah Socolar, M.P.H.
Directors, Health Reform Program
Boston University School of Public Health, Boston, Massachusetts

"How Big Pharma Manipulates Drug Prices and Harms Consumers"
Alex Sugerman-Brozan, Esq.
Director, Prescription Access Litigation Project (PAL), Boston, Massachusetts

"Ten Months of Medicare Part D Prescription Drug Plan:
Drug Utilization and Formulary Issues"
Sebastian Schneeweiss, M.D., Sc.D.
Harvard School of Public Health, Boston, Massachuwetts

"Pharmaceutical Industry Strategy for Medicare Part D"
Robert Kemp, Ph.D. (Econ)
Newcastle Health Economics, Bluffton, Ohio

"Putting It All Together- Where Are We? Where Are We Going?"
Steven W. Schondelmeyer, Pharm.D., Ph.D.
College of Pharmacy, University of Minnesota, Minneapolis, Minnesota

Closing Remarks
Fred S. Mayer, R.Ph., M.P.H.

See individual abstracts for presenting author's disclosure statement and author's information.
Organized by: Alcohol, Tobacco and Other Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Region IX
Health Care Financing
Administration

Refer to: MCD-BCG-CAW

75 Hawthorne Street
4th Floor
San Francisco, CA 94105-3903

January 31, 1997

Frederick S. Mayer, R.Ph., MPH
Pharmacists Planning Service, Inc.
P.O. Box 1336
Sausalito, CA 94966

Dear Mr. Mayer:

I am writing in response to your phone call of January 24, 1997. As you requested, I have enclosed a copy of the finalized section on "Measuring Quality of and Access to Pharmacy Services in Managed Care Plans," which has been included in HCFA's Managed Care Pre-Implementation Review Guide.

We are currently investigating the issues you outlined in your letter of January 14, 1997 regarding access to pharmacies and prescribed drugs in the Fresno area. We have asked the State Department of Health Services to analyze the information you provided, and will notify you of the results of the State's analysis and our investigation as soon as they are completed.

As promised at our last meeting, we have requested HCFA's Office of General Counsel to analyze the Regulatory Flexibility Act's applicability to the Two-Plan program and whether an economic impact study is required. We expect to get an answer within the next few weeks.

Finally, we have not received notification from the State or either of the contracting plans in Los Angeles that there will be a delay in the implementation of Two-Plan in that County.

I hope that the above information is useful. Please call me at (415) 744-3596 if you have further questions.

Sincerely,

Cynthia A. Williams

Cynthia A. Williams
Health Insurance Specialist
Division of Medicaid

Enclosure

Measuring Quality of and Access to Pharmacy Services in Managed Care Plans

ADMINISTRATION AND OVERSIGHT

- What services are included in your pharmacy benefit?

- Does the Plan contract with a PBM?
  - what services have been contracted out, and what services are conducted by Plan staff?
  - how much involvement does the Plan have in administration and oversight of PBM operations?
  - how is the PBM reimbursed for the services it provides?

- What data elements (performance standards, services provided, encounter data, etc.) does the Plan require the PBM to report?
  - how frequently does the Plan require data submission?
  - what types of analysis are done on the data submitted, and in what form is feedback provided to the PBM?

  - review the PBM's provider contract with its pharmacists.
  - review the PBM's contract with the Health Plan.

ACCESS

- How was the pharmacy network developed?
  - were contracts offered to any willing provider?
  - how were pharmacists informed about the Plan and how to participate?
  - did you define"traditional pharmacy providers?" Do you have a policy about the inclusion of traditional providers in the network? Were special provisions necessary to make sure they are part of the network?

- What does the pharmacy network look like?
  - what percent chain versus independent?
  - are pharmacies geographically accessible?
  - does the network provide cultural/linguistic access? How is this measured?
  - what area pharmacies were not included in the network and why?

- How was the formulary developed?
  - what involvement does the Plan have in developing/changing the formulary?
  - are pharmacists and providers from the community able to have input into formulary decisions?
  - how does the Plan's formulary compare to the DHS Medi-Cal formulary?

- What rates are offered for pharmacy services, and who developed them?
  - how did local pharmacists react to the rates?
  - did rates have to be adjusted for any particular area in order to ensure access to pharmacy services?
  - what professional services are included in the pharmacy reimbursement rate (e.g., patient counseling)?
  - are pharmacists included in any provider incentive programs or risk sharing arrangement your Plan offers?

- What special pharmacy programs does your plan offer (e.g., asthma or diabetes education)?

- Are you aware of any pharmacies which have closed or have predicted they will go out-of-business because of managed care? If yes, how will this affect access?

QUALITY

- How does the Plan/PBM ensure the quality of pharmacy services delivered by network pharmacists?
  - what indicators of quality are measured (e.g., distance traveled to pharmacy, waiting time for prescription, language needs met, patient counseling occured, patient satisfaction surveys)?
  - what format is used, and how frequently are these measurements collected?
  - how does Plan ensure that patient counseling occurs are required by State law?
  - does the Plan/PBM offer pharmacists any incentives to improve quality? Please explain.

- What utilization data is collected by the Plan?

Special Medicare Part D Programs - HOLD THE DATES

January 25-27, 2007	**Families USA, Health Action '07** **Renaissance Mayflower, Washington, DC** **(650 consumer nonprofit organizations)**
January 29, 2007	**PPSI's Special Medicare Workshop** **Bill Graham Auditor., San Francisco (8-10 a.m.)**
February 18, 2007	**PPSI's Wm. R. Bacon Memorial Breakfast during the CPhA Annual Meeting** **Wyndham Hotel, Palm Springs; 7 - 9 a.m.**
March 18, 2007	**PPSI's Medicare program during American Pharmacy Association Annual Meeting (APhA)** **Marriott Downtown, Atlanta, GA (7 - 9 p.m.)**
August 30-31, 2007	**PPSI 16th Annual International Public Health and Pharmacy Issues Conference** **Beijing, China (prior to FIP/Beijing/Sept. 1)**

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Posted on Mon, Oct. 23, 2006 email this print this reprint or license this

Medco Health pays $155 million to settle fraud, kickback charges

LINDA A. JOHNSON
Associated Press

TRENTON, N.J. - Prescription-benefits manager Medco Health Solutions Inc. has agreed to pay $155 million in fines to settle fraud, kickback and other charges brought by federal prosecutors in Philadelphia in a whistleblower case dating to 1999.

The agreement, announced Monday by Pat Meehan, U.S. attorney for the Eastern District of Pennsylvania, involves multiple cases of alleged wrongdoing by Medco, the nation's No. 2 pharmacy benefit manager. The settlement comes nearly six months after the two sides announced an agreement in principle shortly before a trial was to begin.

"This settlement and others like it represent a sweeping change in the way pharmacy benefit managers do business," Meehan said in a statement, noting his office reached a $137 million settlement last year with Medco's biggest competitor, Nashville, Tenn.-based Caremark Rx Inc.

"Hidden financial agreements between PBMs and drug manufacturers and health plans, along with the bottom-line pressures of management, can influence which drugs patients receive, the price we all pay for drugs and whether pharmacists serve patients with their undivided professional judgment," Meehan said.

Franklin Lakes-based Medco said in a statement that there was no finding of wrongdoing by the company or any of its people, an agreement typical in government prosecutions of corporations.

"Even though we did nothing wrong, for our company and our clients it is the right decision to put these aged matters in the past," Medco said in a statement.

Among other charges, Medco was accused of paying health-insurance plans kickbacks to obtain their business and of soliciting kickbacks from drug manufacturers to favor their drugs over competitors' products, partly by illegally pressuring pharmacists and doctors

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- PHILLYfunguide.com
- Bucks Midweek
- Montco Midweek
- Northeast Times
- Taste of Phila.
- DeMarco's Italian Specialties
- PhillyNeighborhoods.org
- Homes and Living
- Beach and Bay Homes
- Active Adult Housing
- My Wedding

THE DAY IN PHOTOS

» Today's photos

» Photo Gallery

to switch prescriptions. Medco also was accused of destroying patient prescriptions when its mail-order pharmacies did not fill them as quickly as required by its insurance plan contracts.

Those issues were brought to light by three whistleblowers, Associate U.S. Attorney Jim Sheehan said in an interview. One of them was a government informant and the other two were pharmacists employed at Medco's Las Vegas pharmacy who told the government the operation was poorly run, with prescriptions with the wrong number of pills or other problems being shipped to customers anyway.

To settle those allegations, Medco will pay the government $137.5 million, Sheehan said. Medco also must set up a strict program to ensure it complies with all Medicare requirements and pharmacy practice requirements, with both an independent reviewer and the U.S. Attorney's Office reviewing its records annually for five years, he said.

Meanwhile, Medco will pay an additional $9.5 million to settle other civil charges in a case that Meehan's office expects to announce soon, Sheehan said.

The remaining $8 million will cover a third case, Sheehan said, involving a Medco program that helped its health plan clients get reimbursed by Medicare for diabetes testing supplies used by retired workers. Medco, which used a third-party contractor to run that program, reported problems with it to the U.S. Attorney's Office and ended the program, Sheehan said.

"What their contractor did was to create false documents to get payment from Medicare," Sheehan said.

Medco announced the tentative settlement on May 5, when it reported on its first-quarter profit. That quarter, Medco took a charge of $163 million before taxes, or 32 cents per share, to settle multiple federal legal cases.

The issues covered by the $163 million charge included inflating the drug prices government health programs paid to Medco, the company said at the time.

Medco handles prescription benefits for about 58 million Americans, either by processing electronic claims from retail pharmacies or by shipping medications directly from its dozen mail-order pharmacies around the country.

In trading on the New York Stock Exchange Monday, Medco shares rose 12 cents to $57.60.

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On the Net: http://www.medco.com

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Withholding Information by a PBM

In this month's case, pharmacies in California file a lawsuit against PBMs in an effort to hold them to a legally mandated standard of conduct.

Jesse C. Vivian, BS Pharm, JD
Professor, Department of Pharmacy Practice, College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan

It seems to be a reccurring theme: Pharmacy benefit managers (PBMs) establish themselves as the best way to hold down soaring pharmaceutical drug prices by managing the costs for employer groups or others that provide a prescription drug benefit for employees. These groups agree to pay the PBMs for the cost of drugs dispensed by pharmacies, along with a management fee. But after awhile, it occurs to the purchasers of this benefit that they may not be getting the best deal from the selected PBM. The PBMs get rebates from manufacturers and enjoy other areas of profit that they do not share with the purchasers. For years, PBMs have fought against any potential regulations that would make their billing practices more "transparent." Nevertheless, every year or so parties to these agreements end up in litigation with claims against the PBMs for breach of contract or failure to honor fiduciary duties. This column has addressed these issues several times over the past five years.[1]

Along comes a new case that illustrates the extent that state governments and pharmacies are allowed to go to in reviewing PBM practices.[2] The litigation was spearheaded by a large number of individual- and chain-owned pharmacies claiming that TFI Managed Care Services, a California PBM, and many other PBMs, failed to live up to the duties required by the California statutes on economic audits and adjustments to costs and fees on a periodic basis.[3]

Background

There is a long history behind this battle. In 1981, the California Pharmacists Association had a bill introduced in the state legislature that would require PBM reimbursements at customary charges made by pharmacies rather than the rates unilaterally set by PBMs. After intense lobbying by both the pharmacy representatives and those representing the PBMs, the bill that passed required PBMs only to conduct or obtain the results of biannual studies of a statistically significant sample of California pharmacies' retail drug pricing for pharmaceutical dispensing services to private uninsured customers. The PBMs then had to supply copies of those studies to "clients" on whose behalf the PBMs perform studies. The legislation came to be known as the "Prescription Drug Claims Processors Act," which is the legal name in California for regulating what everybody else calls PBMs. The act intended to regulate the relationships between the pharmacies, the PBMs, and their clients, referred to as the "third-party payors," which encompass a large variety of groups, including health insurance companies, self-insured employer groups, and union health and welfare plans.

As the court envisioned the act, it stated:

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A customer goes to a pharmacy with a prescription and presents both an insurance card and a copay to get the prescription. The pharmacy fills the prescription from inventory. The pharmacy then submits a claim to a PBM for reimbursement. The pharmacy usually has a contractual relationship with various PBMs to assist in performing claims processing services. A PBM coordinates certain aspects of the reimbursement relationship between pharmacies and third-party payors. The PBM processes the pharmacy's claim for reimbursement and pays the pharmacy reimbursements in the amount it unilaterally sets. The PBM, which handles claims for several third-party payors, then submits the claim to the payor and gets paid.

Legal Issues in the Trial Court

One of the more interesting aspects of this case is that the pharmacies were trying to get the state to enforce the law, because the pharmacies had very limited authority of their own to make the PBMs play by the rules. Frustrated by the apparent lack of cooperation from the state regulators, the pharmacies filed a lawsuit claiming that they were injured by the defendant PBMs for not doing the required audits and surveys and passing that data on to the third-party payors under contract to establish and maintain a prescription drug benefit.

However, the pharmacies could not point to any direct economic damages, because no one knows what would have resulted if the PBM had done what it was supposed to do. Being able to point to a specific "injury in fact" is one of the most basic notions of jurisprudence. In addition, there is a requirement that the plaintiffs must have legal "standing" to bring the lawsuit in the first place. Standing is a concept used to decide if the plaintiff actually has some proximity to the intent of the laws. In other words, the pharmacies had to claim that they were an intended beneficiary of the statues in question.

To illustrate the point, assume your state requires that all semi-trucks driving on state-owned roads must have an annual inspection and be certified as safe. Assume one of your loved ones is run over by a truck. You sue the truck owner for damages caused by the death of your loved one. During the course of the litigation, you discover that the truck was not certified as safe at the time of the accident. While the absence of a required registration might be an issue of contention, it would not serve as your only basis for a claim against the truck owner, because there is no indication that any one individual should be protected by that statute. Put slightly another way,

A Right to Refuse? Readers Weigh In

U.S. Pharmacist *received several comments from readers expressing their viewpoints regarding the August Legal Considerations column "Intervention or Unwanted Intrusion?" The following is a sampling of the responses.*

"I was glad to see you give time to the issue of whether or not pharmacists should dispense ECs. I am a women's health nurse practitioner (NP) who was caught up in this same issue a few years ago. In the end, I sought out another position, as did several coworkers. Some even retired to prevent facing such a dilemma. Instead of working as an NP now, I am an HIV Coordinator in public health. I work as an NP one day each week in order to remain certified. I have no regrets on not issuing ECs. I feared that God would be displeased if I assisted someone who was intentionally trying to disrupt a fertilized egg. That stage, for me, is the beginning of pregnancy. Thank you for your comments on the subject."

—Maureen Nichols, BS, BSN, MSN
Alabama NP

"This ongoing question of whether pharmacists should be able to refuse dispensing emergency contraception based on their personal beliefs is specious at best. Beliefs do not come into it. The answer for me is clearly no. The reason is because of what may come next if conscientious objection is allowed to intervene. Do pharmacists then have the prerogative to refuse dispensing regular oral contraceptives because their belief system teaches otherwise? Or is insulin withheld because, in the pharmacist's opinion, an overweight person's diabetes is their own fault? After all, their real problem is 'knife-and-fork' disease, and they would not be in this fix if they had better self-discipline. May they with impunity refuse to dispense an antibiotic for the treatment of what they (and knowledgeable others) consider to be a viral infection? How about refusing an opioid analgesic because the reason for a patient's acute pain should be healed by now, or their chronic pain condition ought to have been well controlled long ago? Or maybe I'll refuse to fill a prescription for an HIV/AIDS antiviral medication because the patient's affliction is due to their free choice of engaging in behaviors that are the medical equivalent of dropping an atomic bomb on their immune system?

"How many other such choices can you think of that individual pharmacists might make and justify by invoking righteous indignation? In view of our society's apparent tilt toward neoconservatism, perhaps faith-based science has insinuated itself into pharmacy school curricula. Or maybe I am just an old fogey who is out of touch with modern theories of pharmacy practice and professionalism."

—Lynn J. Maland, RPh
Salt Lake City, UT

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there is "no private right of action" contemplated by the law. In this instance, one should conclude that while there is an injury in fact, you do not have standing to claim injury as a result of the truck being uncertified.

To get around these barriers, the pharmacies claimed they suffered a "procedural injury" as a result of the PBMs' failure to follow the mandates of the state statutes. At this stage, the PBMs argued

The pharmacies were trying to get the state to enforce the law, because the pharmacies had very limited authority to make the PBMs play by the rules.

that the alleged third-party payors' use of the information to the benefit of the pharmacies was too remote to create standing. They went one step further by speculating that if the studies were done and sent to the third-party payors, there was no requirement to use them in the event that they even read them.

On July 10, 2004, the judge at the trial level agreed with the PBMs and threw the pharmacists' complaint out the door.[4] The pharmacists showed their tenacity by taking their case to the next level, seeking a reversal from the federal Ninth Circuit Court of Appeals. Two years later, in June 2, 2006, the appeals court published its findings.

Court of Appeals' Findings

The appeals court noted that "to satisfy the injury in fact requirement, a plaintiff asserting a procedural injury must show that the procedures in question are designed to protect some threatened concrete interest of his that is the ultimate basis of his standing."[4] Furthermore, the plaintiff must "establish 'the reasonable probability of the challenged action's threat to [his or her] concrete interest.'"[4] In applying these standards to the case at hand, the court noted that the statute under review requires "prescription drug claims processors to conduct or obtain the results of a study or studies identifying the fees, separate from ingredient costs, of all, or of a statistically significant sample, of California pharmacies, for pharmaceutical dispensing services to private consumers."[5] Another provision calls for the study report or reports obtained in accordance with the act to be transmitted by certified mail

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by each prescription drug claims processor to the chief executive officer or designee of each client for whom it performs claims processing services no less often than every 24 months. The act goes on to state that violations of these provisions may result only in imposition of a civil remedy. Any owner of a licensed California pharmacy shall have standing to bring an action seeking a civil remedy pursuant to this section as long as his or her pharmacy has a contractual relationship with, or renders pharmaceutical services to, a beneficiary of a client of the prescription drug claims processor, against whom the action is brought.[6]

The appeals court concluded that under these provisions, the legislature intended to give the pharmacies the ability to enforce PBMs' obligations to provide certain studies to PBM third-party payor clients. However, before proceeding, the law still requires the pharmacies to show that the procedures are designed to protect some threatened concrete interest.[7]

The pharmacies argued that the act requires the PBMs to make studies available to third-party payors. They go on to claim that these studies would reflect the true market rate of return for pharmacy prescriptions. The pharmacies concluded that "the legislature intended that by supplying those involved in the transactions with accurate information regarding free market pricing for the drugs, the market and third-party payors could make informed decisions about fair reimbursement rates to be paid or received for the provision of pharmaceuticals to plan participants as compared to the rates PBMs were currently imposing on pharmacies." The pharmacies also claimed that recipients of the studies could use the information to evaluate what should be actual market prices, negotiate fairer reimbursement rates, lobby for legislative intervention if necessary, and ascertain payments made to PBMs against those amounts the PBMs pass on to pharmacies.

In a response, coming as no surprise, the PBMs reasserted their claims that were used successfully at the trial level to the effect that use of the information in this manner, to the benefit of the pharmacies, was too remote to create standing. Even if the third-party payors actually received the studies, there exists no requirement that they use them, if they even read them.

To reconcile these conflicting viewpoints, the appeals court dug deep into the legislative history of the act and concluded that the legislature intended that making

these studies publicly available would presumably "require claims processors to present objective data on the range and percentiles of usual and customary charges of pharmacists in the hope that at a time in the future this information will become the basis for reimbursement."[8] This court concluded that the "concrete injury is a lack of information, the denial of which then adversely affects the possibility such information will improve reimbursement rates at some point." In stark contrast to the trial court findings, the appeals court opined that the procedural injury claimed threatens a concrete interest of the pharmacies and is thus sufficient to create injury in fact for purposes of standing and getting a fair hearing on their complaints.

There were a few more wrangling issues, but the bottom line is that the trial court's dismissal of the complaint was overturned. The case will now go back to the trial court judge for further proceedings and, eventually, a trial on the merits of the parties—unless they settle their differences.

Analysis

This is a case about not knowing what you don't know and finding a way to cure your lack of information. To give rise to a procedural injury as a substitute of an injury in fact is a rarely used litigation strategy, because it does not work very often. The federal appeals court went to great lengths to help the pharmacies find a way to address their concerns. The validity of these claims may have been overshadowed by the arrogance of the PBMs. It takes a certain amount of moxie to walk into a federal courthouse and explain to an all-powerful judge that your clients have been ignoring a law for the past 25 years or so because they have no obligation to follow its mandates because they are litigation-proof.[9] The alternate argument also lacked credibility. The PBMs asserted that even if they have some obligations under the law, these plaintiffs do not have the necessary legal status to bring suit against them because they can't show directly how they were harmed by the lack of the PBMs' efforts to record, collect, and disclose their findings to the organizations that they work for. Neither claim was very persuasive or compelling.

The other thing to consider is what forms of retaliation they might suffer in going for the gold in this lawsuit. Here the major PBM players, with their "take-it-or-leave-it" philosophy, could easily nullify their agreement with a pharmacy by departicipating any pharmacy involved in this lawsuit at any time, for any reason, or for no reason at all. The PBMs could also threaten to audit the pharmacy claims for reimbursement and come up with insufferable overpayment amounts. As the lifeblood of any pharmacy, these implicit understandings could be used as powerful deterrents to engage in holding the PBMs up to a legally mandated standard of conduct. The resolve of the pharmacies in California to stand up to the giants of their income for rendering pharmacy services should serve as encouragement to pharmacies across the country that the pendulum of unfair and oppressive terms imposed by PBMs may be starting to swing the other way. At the very least, it should be viewed as a sign that there may be a way to find a better balance of trying to keep health care costs in line but not at the expense of the providers who act in good faith to take care of their patients. Maybe the PBMs will not be forced into operating in complete transparency, but the days of absolute opaqueness are hopefully growing shorter. ■

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1. Vivian J. PBMs on Trial Again. *US Pharm.* 2006;31:52-66, available at: www.uspharmacist.comindex.asp?show=article&page=8_1685.htm; PBMs Under Legal Scrutiny. *US Pharm.* 2005;30:43-47, available at: www.uspharmacist.com/index.asp?show=article&page=8_1643.htm; Drug Benefit Insurance. *US Pharm.* 2005;30:56-60, available at: www.uspharmacist.com/index.asp?show=article&page=8_1552.htm; Any Willing Provider Laws. *US Pharm.* 2003;28:09, available at: www.uspharmacist.com/index.asp?show=article&page=8_1142.htm; State Prescription Benefit Programs. *US Pharm.* 2001;26:07, available at: www.uspharmacist.com/oldformat.asp?url=newlook/files/Phar/ACF234C.htm&pub_id=8&article_id=745.
2. *Beeman & Pharmacy Services v. TDI Managed Care Services*, 449 F 3d 1035, 2006 US APP Lexis 13764, 9th Cir (June 2, 2006).
3. California Civil Code §§ 2527 and 2528.
4. Appeal from the United States District Court for the Central District of California. D.C. No. CV-02-01327-VAP, D.C. No. CV-04-00407-VAP. Virginia A. Phillips, District Judge, Presiding. *Jerry Beeman & Pharm. Servs. v. TDI Managed Care Servs.*, 2004 U.S. Dist. LEXIS 13207 (C.D. Cal., July 10, 2004).
5. California Civil Code section 2527(c). This provision states in full: On or before January 1, 1984, every prescription drug claims processor shall have conducted or obtained the results of a study or studies which identifies the fees, separate from ingredient costs, of all, or of a statistically significant sample, of California pharmacies, for pharmaceutical dispensing services to private consumers. The study or studies shall meet reasonable professional standards of the statistical profession. The determination of the pharmacy's fee made for purposes of the study or studies shall be computed by reviewing a sample of the pharmacy's usual charges for a random or other representative sample of commonly prescribed drug products, subtracting the average wholesale price of drug ingredients, and averaging the resulting fees by dividing the aggregate of the fees by the number of prescriptions reviewed. A study report shall include a preface, an explanatory summary of the results, and findings, including a comparison of the fees of California pharmacies by setting forth the mean fee and standard deviation, the range of fees, and fee percentiles (10th, 20th, 30th, 40th, 50th, 60th, 70th, 80th, and 90th). This study or these studies shall be conducted or obtained no less often than every 24 months.
6. California Civil Code section 2528.
7. Citing to *Idaho Conservation League v. Mumma*, 956 F.2d 1508, 1514 (9th Cir. 1992) "The personal injury requirement will be met only if the alleged harm is 'distinct and palpable and not abstract or conjectural or hypothetical.'"
8. Staff Comment to the report of the Assembly Committee on Finance, Insurance, and Commerce (cited in ARP Pharm. Serv., *Inc. v. Gallagher Bassett Serv.*, Inc., 135 Cal. App. 4th 841, 850, 38 Cal. Rptr. 3d 67 (Cal. Ct. App. 2006) (vacated and request for rehearing granted)). As the Department of Insurance noted in the Enrolled Bill Report, even if "the bill is fairly innocuous in its impact... it may help identify areas for cost-containment in the future."
9. "Litigation-proof" means immune from liability.

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Support CMS efforts to make Part D data available for research

CMS is soliciting comments on the proposed rule for collection of Part D (Medicare drugs) data for evaluation and research.

If you wish to support this, comments are due by *12/18/06*. The full text appears in the Federal Register, vol. 71, no. 201, 10/18/06, pages 61445-61455.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4119–P]

RIN # 0938–AO58

Medicare Program; Medicare Part D Data

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. The Secretary needs to use this data because other publicly available data are not, in and of themselves, sufficient for the studies and operations that the Secretary needs to undertake as part of the Department of Health and Human Service's obligation to oversee the Medicare program, protect the public health, and respond to Congressional mandates.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 18, 2006.

ADDRESSES: In commenting, please refer to file code CMS–4119–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4119–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address *only:* Centers for Medicare &

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Session 4240.1

Tuesday, November 7: 2:30 PM-4:00 PM
Room 54 Boston Convention Center

A Panel Discussion

Drug Manufacturers, the FDA, and U.S. Health Care:

How Can the Public Be Assured of Access to Safe, Effective Medicines?

The past decade has brought increasingly sharp criticism of the drug industry by both health professionals and the general public. The industry is widely seen not only as promoting development of groundbreaking new therapies but also as wielding its economic power to exert undue, self-serving influence over scientific, legislative, and regulatory processes; training of professionals; and information flow among scientists, health professionals and the public. Further, it is seen as abusing the patent system to price medicines beyond the reach of many who need them while straining government finances as well.

The panel will examine these criticisms and discuss the need for reforms.
Each panel member will make a three-minute opening statement.
The moderator will then pose questions, with panelists offering one-minute responses.
Audience participation will follow.

Panel:*

John D. Abramson – Harvard Medical School; author, "Overdosed America"

Marcia Angell – Harvard Medical School; author, "The Truth About the Drug Companies"

David J. Graham – FDA Office of Surveillance & Epidemiol.; recipient, APHA Award for Excellence

Jerome P. Kassirer – Tufts U. School of Medicine; author, "On the Take"

Deborah Socolar – Boston U. School of Public Health; Director, BUSPH Health Reform Program

Moderator:

Merrill Goozner – Center for Science in the Public Interest; Dir., CSPI Integrity in Science Project

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* Listed participants will speak on their own behalf, not as representing their institutions or agencies.

5 widely used drugs called unsafe

FDA officer says conflicts of interest compromise agency

By Marc Kaufman
WASHINGTON POST

WASHINGTON — A veteran Food and Drug Administration safety officer Thursday told a Senate hearing inquiring into the abrupt recall of the arthritis drug Vioxx that five other widely used drugs should be either withdrawn or sharply restricted because they have dangerous side effects.

Describing the agency that he works for as incapable of stopping dangerous drugs from coming to and staying on the market, David Graham, associate director of the Office of Drug Safety, told the senators that the FDA's role in reviewing and approving new drugs sometimes conflicted with its duty to address safety issues.

David Graham

Asked by Sen. Jeff Bingaman, D-N.M., to identify the five drugs, Graham hesitated and then listed them to the startled hearing room: the popular cholesterol-lowering drug Crestor, the weight-loss drug Meridia, the painkiller Bextra, the acne medication Accutane and the asthma medication Serevent.

Each poses different issues, Graham said in answer to questions from senators, but all require more aggressive action by the FDA.

AstraZeneca's Crestor, he said, poses risks of kidney failure and a rare muscle disease; Abbott Laboratories Inc.'s Meridia is of little use and has cardiovascular side effects; Roche's Accutane can cause birth defects if used by pregnant women; Pfizer's Bextra carries cardiovascular risks similar to those linked to Vioxx; and GlaxoSmithKline's Serevent increases the risk of dying of asthma. The makers of all five drugs later defended their products vigorously.

Dr. Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, said the agency already had taken steps to alert consumers to those drugs' safety concerns. That includes heightened warnings for Serevent; a tougher risk-management plan to ensure pregnant women don't use Accutane, and an upcoming advisory committee hearing regarding Bextra.

A 20-year veteran of the FDA, Graham has played a significant role in the withdrawal of nine drugs over the past decade, and his highly unusual attack on his own agency astonished many in the room. He called the FDA's handling of Merck & Co.'s Vioxx — which he said should have been pulled from the market years ago — the most distressing episode of all and a "profound regulatory failure."

"I would argue that the FDA as currently configured is incapable of protecting America against another Vioxx," Graham said in his scathing assessment. "The scientific standards (the FDA) applies to drug safety guarantee that unsafe and deadly drugs will remain on the U.S. market."

Citing estimates he said were based on the results of Merck's own clinical trials, Graham said between 88,000 and 139,000 Americans had probably had heart attacks or strokes as a result of taking Vioxx, and that 30 to 40 percent had probably died.

Graham also contended that FDA had an inherent conflict of interest that triggered "denial, rejection and heat" when safety questions emerged about products it had approved.

Graham's sentiments were endorsed at the hearing by two other drug safety experts, but they were disputed by a ranking FDA official as "not the FDA that I know."

Sandra Kweder, deputy director of the Office of New Drugs, said the agency was dedicated to protecting consumers and that drug safety was at the heart of its activities. She acknowledged, however, that "clearly, there's concern by the public and this committee that the system isn't working as well as it should, and we need to address that."

Asked about the five drugs that Graham identified as needing immediate action, Kweder said, "I don't have reason to believe that set of five drugs gives more reason for concern than any other set."

Graham's revelations and criticisms were the centerpiece of the hearing called by Sen. Charles Grassley, R-Iowa, chairman of the Senate Finance Committee and an increasingly sharp critic of the FDA. Following Graham's comments, Grassley pointedly warned agency officials against disciplining Graham in any way.

Grassley also suggested that an independent board of drug safety may be needed to ensure the safety of medications after FDA approval. An "awful lot of red flags" were raised before Vioxx was withdrawn, said Grassley, and the agency disdained, rather than listened to, its own reviewers.

Merck CEO Raymond Gilmartin came to the defense of the FDA and his company's actions in dealing with the issues around Vioxx, a heavily advertised and hugely profitable drug until it was abruptly recalled in September. He said the company had no scientific reason to withdraw the drug until it heard clear negative results reported by the safety monitoring committee of a clinical trial. At the time, Gilmartin said, his own wife was regularly taking the drug.

"Throughout Merck's history, it has been our rigorous adherence to scientific investigation, openness and integrity that has enabled us to bring new medicines to people who need them," Gilmartin said. "I am proud that we followed that same rigorous scientific process at every step of the way with Vioxx."

One of a class of painkillers known as COX-2 inhibitors that are widely used by arthritis sufferers, Vioxx was introduced in 1999. It was withdrawn after researchers halted a clinical trial because patients taking Vioxx were experiencing twice as many heart attacks and strokes as patients taking a placebo, but witnesses testified there had been suggestions of possible cardiovascular risks going back the mid-1990s.

Officials of the companies whose drugs were cited by Graham all said they were surprised by his testimony.

Carolyn Glynn, a spokeswoman for Roche, said it had long recognized that Accutane required special handling because of its known connection to birth defects.

AstraZeneca, the maker of Crestor, said in a statement that "to date, the FDA has not given the company any indication of a major concern regarding Crestor, and the comments today are inconsistent with past public statements from the FDA."

Abbott Laboratories issued a statement defending its weight-loss drug Meridia. "Obesity remains one of the leading health epidemics in the U.S., and Meridia is one of the few effective drugs that are currently available," it said.

GlaxoSmithKline stood by its asthma drug Serevent, saying it was "safe and effective when used appropriately."

Pfizer spokeswoman Susan Bro said its Cox-2 drug, Bextra, "has been found safe and effective when used as indicated." She noted that the company had already "committed to conducting further studies to confirm the longer-term cardiovascular safety profile."

The Associated Press contributed to this report.

Worrisome drugs?

Five drugs cited by a Food and Drug Administration official as the worst examples of those that remain on the market despite safety concerns:

- **Accutane**, a treatment for severe acne linked to birth defects and fetal death when used by pregnant women.
- **Bextra**, a painkiller found in a recent study to more than double the risk of heart attacks and strokes among patients with heart disease.
- **Crestor**, an anti-cholesterol drug linked to a muscle-destroying side effect and acute renal failure.
- **Meridia**, an obesity treatment linked to heart problems and, among pregnant women, stillbirths, miscarriages and birth defects.
- **Serevent**, an asthma medication that a study in England linked to increased deaths.

Source: Associated Press

NOTE - ENCLOSED

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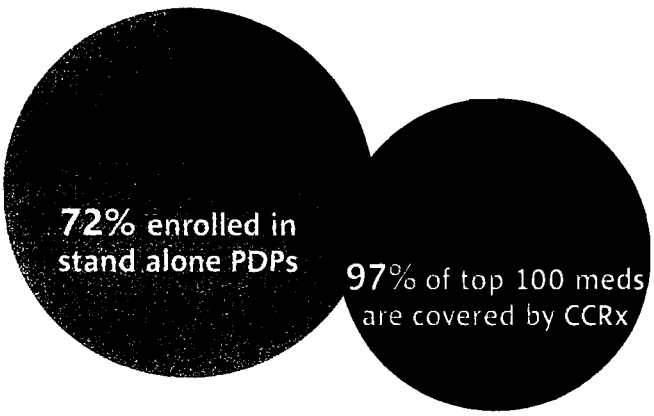
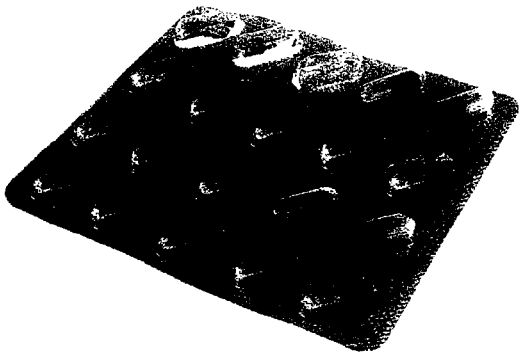
You Are in Good Company.

More than 72% of Medicare beneficiaries with Part D coverage are enrolled in stand-alone Prescription Drug Programs like CCRx, while 18% are enrolled in Medicare Advantage Prescription Drug Plans, according to an Avalere Health analysis of Centers for Medicare & Medicaid Services (CMS) data.

The CCRx drug list (formulary) covers 97% of the top 100 medications taken by Medicare beneficiaries. This percentage applies to medications allowed under Part D.





MemberHealth #1

Of the top 20 preferred brand medications most often prescribed to seniors, CCRx covers more than any other Part D provider—17 out of 20 medications are on our preferred drug list.

Source: Procter & Gamble Pharmaceuticals Research analysis of data from the Centers for Medicare and Medicaid Services

New Additions to the CCRx List of Covered Drugs

Medication	Tier	Common Uses
finasteride (generic Proscar®)	Generic	Enlarged prostate
simvastatin (generic Zocor®)	Generic	High cholesterol
meloxicam	Generic	Pain, Arthritis
Levemir®	Preferred Brand	Diabetes
Azilect®	Brand	Parkinson's disease
Innohep®	Brand	Blood clots
Lacrisert®	Brand	Severe dry eyes
Sanctura®	Brand	Overactive bladder
Tygacil®	Brand	Infections (antibiotic)
Other Changes to the CCRx Formulary		
Crestor® — **Now a preferred brand medication**	Preferred Brand	High cholesterol

Drug Cost Containment

Washington D.C.
January 23, 2004

Mark Gibson
Program Officer, Milbank Memorial Fund

Why Drug Cost Containment?

- Cost is Barrier to Access
  - Reduce waste
  - Top value for dollar spent
  - Lower cost = greater access
- This is Real Money
- Improving Health
  - IOM 18,000 Deaths/yr.
  - Fewer cuts to other health services

Impact on Public Programs

- Health care has no intrinsic value
- Public budgets are finite
- Zero sum health care trade offs
  - 37 Reduce/Freeze providers
  - 27 Reducing eligibility
  - 17 Increasing co-payments
  - 25 Reducing benefits

Finding Value in Drug Purchasing

- Value traditionally determined by markets
  - Quality
  - Cost
- Drug Purchasing is not a traditional market
  - Payer ≠ Purchasing Agent ≠ Consumer
  - Sellers Control Quality Information
  - Purchasing agent bears no risk
  - Neither payer, nor purchasing agent have current cost information

Preferred Drug Lists — An Attempt to Create a Functional Market for Drugs

- Making a clinical judgment (Quality)
- Making a price comparison (Cost)
- Determining the exceptions process (Value)

Making a Clinical Judgment

- If it's in the class
- Expert process
- Systematic Review of Evidence

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Making a Price Comparison

- Analyzing prices after the fact
- Reference pricing/supplemental rebates
- Prospective bidding

Determining an Exception Process

- PDL Advisory
- Simple "Generic" style substitution
- Prior authorization
  - Phone call
  - Written submissions

Enhancing the Quality of Medical Evidence Used in Coverage and Treatment Policies

- Oregon requires effectiveness first
- Collaboration with EPC
- Use of systematic reviews
- Open public process

Information Strategy

- Focus on specific classes
- Evidence-based
- Emphasize key questions
- Systematic review—removes bias
- Credible public process

OHSU Evidence-based Practice Center

- AHRQ Center
- Contracts with state for drug class reviews.
- Credible, responsive source of comprehensive information.
- Reports to local decision making body.

EPC Strengths

- Emphasize getting questions right
- State of art methods for conducting systematic reviews
- Accustomed to timelines, deliverables
- Extensive, external peer review
- Process and result fully disclosed

Expert Weakness

- Experts may underplay controversy or select only supportive evidence
- Without systematic approach bias may be introduced
- Experts may ask good research questions but the wrong questions for patients and providers
- Experts may not be aware of all evidence
- Sometimes are not willing to disclose fully their evaluation process back to importance of disclosure to consumers and advocates documents

Systematic Review Process

- Problem formulation/key questions
- Find evidence
- Select evidence
- Synthesize and present
- Peer review and revision
- Maintain and update

First Four Classes — Oregon Conclusions

1. **PPIs/heartburn** — "no significant demonstrable differences among them"
2. **Long-acting opioids** — "insufficient evidence to draw any conclusions about the comparative effectiveness"
3. **Statins/cholesterol lowering** — "evidence supports the ability of lovastatin, pravastatin and simvastatin to improve coronary heart disease clinical outcomes."
4. **NSAIDs** — "no significant clinical differences"

Next Classes — Oregon

- **Estrogens**---"No studies showed any difference between estrogen preparations."
- **Triptans**—"Using 2-hour pain free...oral rizatriptan 10 mg appears to be the most efficacious."
- **ACE Inhibitors/Calcium Channel Blockers**— thousands of studies meeting criteria—due in Summer '03

Next Classes — Oregon

- **Incontinence drugs**---"evidence does not demonstrate significant differences in objective or subjective efficacy, adverse events or withdrawals."
- **Skeletal Muscle Relaxants**---"the evidence does not support any conclusions for the comparative efficacy or safety....for musculoskeletal conditions. "
- **Oral Hypoglycemics**---"patients on glyburide had greater risk reduction of progression of retinopathy than those on chlorpropramide....chlorpropramide has a less favorable adverse effect profile...insufficient evidence on other sulfonylureas and non-sulfonylurea secretagogues."

What is Next

- Globalize the evidence
- Localize decision making

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Center for Evidence-based Policy

- Focus on informing state policy makers of the evidence regarding key issues
- Funded by public and private participants sharing in the cost
- Each project governed by the participants
- Participants identify topics and key questions

First Project—Drug Effectiveness Review Project

- Continue drug class reviews focusing on comparative effectiveness to support preferred drug list, formulary or disease management activity
- Focus on the most common 25 drug classes
- Update every 6 months
- Each participant uses local decision makers to draw conclusions from the evidence for their use

Drug Effectiveness Review Project

- Systematic evidence-based reviews done by a network of Evidence-based Practice Centers.
- EPCs in several regions of the country.
- Experienced, credible, reliable.
- Used to deadlines, working in public domain, free of conflict of interest.
- Work is peer reviewed.
- Process and findings are fully disclosed.

What is Next

- **Localize Decision Making**

1. Organize public and private decision makers
2. Explicit, public process
3. Externalize bias
4. Eliminate conflict of interest

More Information

- Reports at **oregonrx.org**
- Email comments/questions to gibsomar@ohsu.edu
- Call Center for Evidence-based Policy (503) 494-2182

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Practitioner-Managed Prescription Drug Plan (PMPDP)
All drugs listed below were evaluated by the Health Resources Commission (HRC) using an evidence-based review process. HRC identified drugs of similar or superior benefit when used as the initial treatment for the majority of patients. DHS limited the list of identified drugs to the most cost effective. Therapeutic prior authorization (PA) requirements still apply to drugs listed in the PDL classes (OAR 410-21-0040).

Plan Drug List (PDL)
Note: (**) This drug represents the benchmark drug for the class.

ALZHEIMER'S DRUGS:
(**)Aricept
- Excelon
- Namenda
- Razadyne

ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS:
- (**)Enalapril (generic)
- Aceon
- Captopril (generic)
- Lisinopril (generic)
- Uniretic

ANGIOTENSIN II RECEPTOR ANTAGONISTS (AIIRA):
- (**)Cozaar
- Avalide
- Avapro
- Atacand
- Atacand HCT
- Benicar
- Benicar HCT
- Diovan
- Diovan HCT
- Hyzaar
- Micardis
- Micardis HCT
- Tevetin
- Tevetin HCT

BETA-BLOCKERS:
- (**)Toprol XL
- Acebutolol (generic)
- Atenolol (generic)
- Bisoprolol (generic)
- Inderal LA
- Innopran XL
- Labetolol (generic)
- Metoprolol tartrate (generic)
- Nadolol (generic)
- Pindolol (generic)
- Propranolol (generic)
- Timolol (generic)

CALCIUM CHANNEL BLOCKERS:
Dihydropyridines:
- (**) Norvasc
- Nicardipine (generic)
- Nifedipine (generic)
- Nifedipine CC tablets (AB generics for Adalat CC)
- Nifedipine XL tablets (AB generics for Procardia XL)
- Sular

Non-Dihydropyridines:
- (**)Verapamil Sustained Action tablets
(AB generic for Isoptin SR)
- Diltiazem IR (generic)
- Verapamil IR (generic)

ESTROGENS:
Oral Products
- (**) Estradiol (generic)
- Menest

Transdermal Products
- (**) Estradiol patch (generic)
- Alora

410-121-0030 Page 6
- Estraderm
- Vivelle

ESTROGENS, cont.
Vaginal Products
- (**) Vagifem
- Premarin

HYPOGLYCEMICS, ORAL:
- (**) Glyburide (generic)
- Glipizide (generic)

INHALED CORTICOSTEROIDS:
- (**) QVAR
- Flovent
- Aerobid, Aerobid-M

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID):
- (**) Naproxen (generic)
- Ibuprofen (generic)
- Indomethacin (generic)
- Piroxicam (generic)

OPIOIDS, LONG-ACTING:
- (**) LA-Morphine Sulfate (generic)
- Levorphanol (generic)
- Kadian
- Methadone HCL (generic)
- Oramorph SR

PROTON PUMP INHIBITORS:
- (**)Prilosec OTC

SKELETAL MUSCLE RELAXANTS:
Antispasmodics for chronic neurological conditions:
- (**) Baclofen (generic)

Acute/chronic musculoskeletal spasms:
- (**)Cyclobenzaprine (generic)

STATINS (CHOLESTEROL-LOWERING MEDICATIONS):
Low/Medium Potency
- (**) Lovastatin (generic)
- Altoprev
- Lescol
- Lescol XL
- Pravachol

High Potency
- Lipitor
- Zocor

TRIPTAN DRUGS:
- (**) Maxalt
- Amerge
- Axert
- Imitrex
- Maxalt MLT
- Relpax
- Zomig
- Zomig ZMT

Nasal
(**) Zomig
- Imitrex

Subcutaneous
(**) Imitrex

OVERACTIVE BLADDER DRUGS:
- (**) Oxybutynin (tablets and liquid)

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Risks from popular medications deta

Bad drug reactions send 700,000 to ER yearly, study says

By Lindsey Tanner
Associated Press

CHICAGO — Harmful reactions to some of the most widely used medicines — from insulin to a common antibiotic — sent more than 700,000 Americans to emergency rooms each year, landmark government research shows.

Accidental overdoses and allergic reactions to prescription drugs were the most frequent cause of serious illnesses, according to the study, the first to reveal the nationwide scope of the problem. People over 65 faced the greatest risks.

"This is an important study because it reinforces the really substantial risks that there are in everyday use of drugs," said patient safety specialist Bruce Lambert, a professor at the University of Illinois at Chicago's college of pharmacy.

Even so, the study authors and other experts agreed that the 700,000 estimate was conservative because bad drug reactions are likely often misdiagnosed.

The study found that a small group of pharmaceutical warhorses were most commonly implicated, including insulin for diabetes; warfarin for clotting problems; and amoxicillin, a penicillin-like antibiotic used for all kinds of infections.

"These are old drugs which are known to be extremely effective. We could not and would not want to live without them. But you've got to get the dose exactly right. Variations, especially on the high side, are really dangerous," Lambert said. He was not involved in the research.

See Drugs, page A11

From page A1

Those aged 65 and older faced more than double the risk of requiring emergency room treatment and were nearly seven times more likely to be admitted to the hospital than younger patients.

The results, from 2004-05, represent the first two years of data from a national surveillance project on outpatient drug safety. The project was developed by the federal Centers for Disease Control and Prevention, the Food and Drug Administration and the U.S. Consumer Product Safety Commission. The study was published in today's Journal of the American Medical Association.

The database included 63 nationally representative hospitals that reported 21,298 bad drug reactions among U.S. adults and children treated in emergency rooms during the two-year period. The tally is based on what emergency room doctors said were complications from using prescription drugs, over-the-counter medicines, dietary supplements or herbal treatments.

The researchers said it translates to 701,547 complications nationwide each year.

"Experts had thought that severe outpatient drug events were common, but no one really had good numbers" until now, said lead author Dr. Daniel Budnitz, a CDC researcher.

Complications included diabetics on insulin passing out from low-blood sugar, excessive bleeding in patients on warfarin and severe skin rashes in patients taking amoxicillin. Drug reactions were severe enough to require hospitalization in about 17 percent of patients. The study did not include information on whether any of the reactions were fatal.

"The numbers are quite troubling," said Jim Conway, senior vice president at the Institute for Healthcare Improvement. The tally underscores that "there is a tremendous number of consumers in the United States taking medication."

The CDC has estimated that about 130 million Americans use prescribed medication every month. U.S. consumers buy far more medicine per person than anywhere else in the world.

Yet a recent study found that doctors' conversations with patients when prescribing new drugs aren't very thorough and that side effects often aren't mentioned. Many of the drugs implicated in the new study require frequent physician monitoring to make sure the dose is correct.

The new findings highlight the need for better doctor-patient communication about use of medicines, Conway said.

The number likely underestimates the number of people who have bad drug reactions outside a hospital setting because many don't get ER treatment, while others who do may have symptoms that are mistakenly attributed to something else, said patient safety expert Dr. David Bates, a professor at Harvard Medical School.

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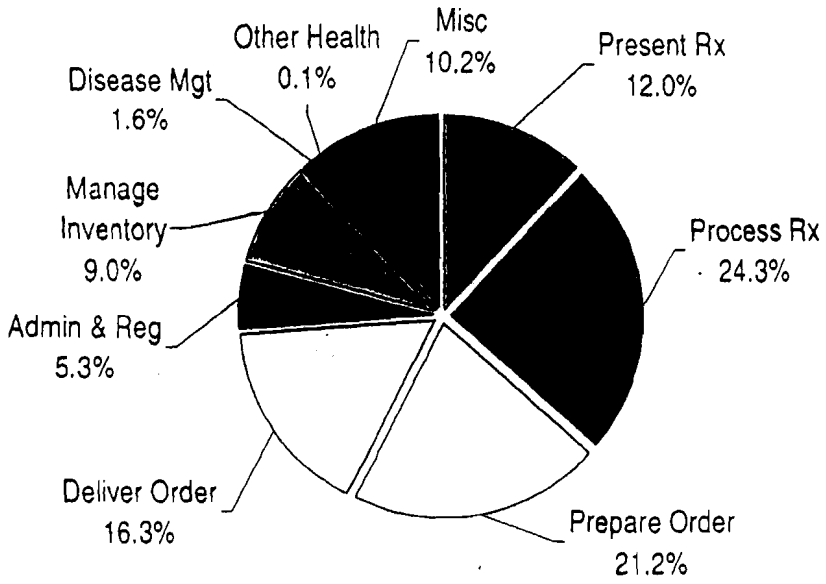
Executive Summary

(21)

Arthur Andersen LLP was engaged to perform an independent study to identify the cost and effort associated with store-based pharmacy related activities. Funding support was provided by the National Association of Chain Drug Stores (NACDS) Education Foundation. The primary purpose of the study was to provide an assessment of the time and associated cost of performing activities. Arthur Andersen LLP was also asked to provide observations and identify opportunities for performance improvement at the stores.

In summary, 73% **of pharmacy personnel staff time was spent on processing orders and prescriptions**, 9% on managing inventory, 5% on pharmacy administration and 13% on other miscellaneous activities. **Pharmacists** are spending over two-thirds (68%) of their time on these activities.

Amount of Time Spent Per Pharmacy Process



Our analysis of the 36 discreet activities associated with processing orders and prescriptions suggests that pharmacists need only be involved in a few of these. We think that pharmacists need to be involved with reviewing and interpreting the prescription, assessing patients' drug therapy (including drug interactions), resolving clinical conflicts, contacting doctors concerning approvals or prescription clarification, and counseling patients about prescription. **Pharmacists spend only 31% of their time on these activities, therefore a significant opportunity exists to transfer pharmacist time to ancillary personnel.**

(5)

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PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

George Paz.
Chairman, CEO
Express Scripts, Inc.

Mark Merritt
President & CEO

December 18, 2006

DEC 22 2006

Leslie Norwalk
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201
RE: CMS–4119–P

Dear Administrator Norwalk:

PCMA appreciates the opportunity to comment on the CMS proposed rule entitled "Medicare Data: Medicare Part D Data." PCMA represents the nations Pharmacy Benefits Managers (PBMs) which provide access to prescription drug benefits to millions of Americans

Overview

PCMA is in agreement with CMS that medical and prescription claims data can be used to discover potential gaps in patient care, trends in the care of Medicare patients, improve the quality of care for Medicare patients, and enhance the efficiency of the Medicare program. In addition, we agree that CMS has a responsibility to collect information from Part D plans and sponsors to administer, evaluate, analyze, and make recommendations relating to the Medicare Part D program.

However, we question whether CMS has the authority under the MMA to use and disclose Part D plans' claims data for the purposes specified in the proposed rule. We believe the unintended effects of implementing the proposed rule as written, would seriously undermine the private sector market-based underpinnings of the Part D program. Specifically, we have concerns about the impact that disclosing such critical, proprietary, and in some cases personal data beyond CMS will have on beneficiaries and the competitive success of the Part D program.

Our comments therefore focus on the following points:

1. **Ensure Beneficiaries Personal Health Information remains protected.**
2. **Maintain protections of proprietary Part D plan data**—The ability of Part D plans to continue to obtain savings for beneficiaries relies on maintaining these key protections.
3. **Establish an appropriate method to use Part D claims data**—Methods such as selecting appropriate data fields, aggregating, and de-identifying the Part D claims data, CMS can achieve the goals of improving the quality of care beneficiaries receive.

Therefore, we offer to provide assistance in developing workable solutions to facilitate the sharing of the data for the purposes outlined in the proposed regulation through different means. PBMs are experts in working with prescription drug data and we believe this expertise could be invaluable to appropriately and effectively take advantage of this critical Part D data. Such solutions could include aggregating, de-identifying by plan, and selecting the appropriate claims data fields that provide sufficient information to carry out the goals of improving beneficiary health set forth in the proposed rule without compromising patient privacy, or proprietary information.

We believe that the MMA and Part D final rule have drawn the proper distinction and balance in how they treat the following levels of data to ensure that program goals are met for beneficiaries, and plans are fulfilling their contractual obligations to CMS:

1) **Information to determine that the program is offering the benefits intended-**

   Various types of aggregate or general program data (such as enrollment, formulary, drug price comparisons, MTMP and quality assurance data) that is collected from Part D plans and used and disseminated for program oversight, evaluation and beneficiary education purposes.

2) **Data that is used by CMS to perform its payment function-**

   Claim-specific data that includes personal health information and is also recognized and protected as proprietary. Its use is restricted to only that necessary for CMS to perform its payment oversight role.

As discussed in more detail below, we believe the proposed rule departs from this approach and we offer the following comments and recommendations.

Privacy of Personal Health Information [Preamble II.B.1]

Without specificity as to who will participate in these data exchanges and why these data exchanges will occur, we believe that beneficiaries will be troubled if they knew their personal prescription data, generated by their plan, was transferred to another private organization or a government-created "chronic care warehouse" without their knowledge or consent. The proposed rule speaks of sharing Medicare beneficiary PHI with other entities under contract with CMS for demonstration programs and other initiatives.

Recommendation:

CMS should not disclose Part D data outside of CMS that could compromise the privacy of personal health information.

Proprietary Information Protections [Sharing Data with Entities Outside CMS]

Competition in Part D is premised on the ability of private entities to protect their proprietary data which Congress, CMS, and the Federal Trade Commission[1] have all confirmed. It is for this reason that CMS, in addition to affording certain data automatic protection under 42 CFR 423.322(f) (based on section 1860D-15 of the MMA), also provided Part D plans an alternative avenue in 42 CFR 423.502(d) for protecting a broader category of data, namely, claiming exemption under Exemption 4 of the Freedom of Information Act ("FOIA"). The basis for this exemption is that: "(1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or, (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value."[2]

As currently drafted, these protections would be circumvented by providing direct access to the data envisioned in the proposed rule.

Recommendation:

Part D claims data and other proprietary data should continue to be subject to the existing statutory and regulatory protections afforded by the MMA, Part D rule, and FOIA Exemption 4.

Such solutions could include aggregating, de-identifying by plan, and selecting the appropriate claims data fields that provide sufficient information to carry out the goals of improving beneficiary health set forth in the proposed rule, without compromising proprietary information.

If any data is provided under the Section 1860D-15 authority, we ask that CMS provide appropriate notice to all relevant stakeholders whose identity or proprietary information is to be disclosed to allow for appropriate FOIA protections to be exercised.

Legal Authority [Preamble I.B, Sharing Data with Entities Outside CMS]

The legal authority to disclose the data in the manner specified in the proposed rule, is cited from Section 1860D-12 which cites Section 1857(e) of the Social Security Act. This authority only allows the Secretary to include such "other" contractual provisions (including requiring information) as the Secretary finds "necessary and appropriate." However, the protection provided to data collected under Section 1860D-15 is not lost simply because CMS seeks to collect the same data under another provision. What it would mean is that the data is now subject to both provisions, and must comply with any requirements and limitations of both.

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[1] See, for example, FTC Staff Letter to Assemblyman Greg Aghazarian, September 3, 2004, where the FTC Staff stated " Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely."

[2] 70 Fed. Reg. at 4332.

Comment:

No provisions under Section 1860D-12 directs or requires the Secretary to disclose the information collected in a manner contrary to the restrictions in Section 1860D-15.

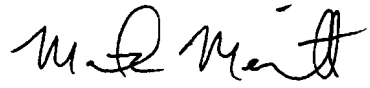
To the extent that CMS wishes to use the data for payment oversight or program integrity services, this is specifically permitted under section 1860D-15(d) and (f) and 42 CFR 423.322(b), and so no further authority to do so is required. This authority also would adhere to existing statutory and regulatory protections.

In addition, we are concerned that CMS uses the broad authority of Section 1860D-12 that CMS could attempt to use the authority of §1860D-12 as the basis for collecting and/or disseminating other sensitive plan information, including rebate and bid information. If such information becomes publicly available the concern is that brand manufacturers will scale back rebates and discounts in fear of such pricing becoming more broadly used in the commercial sector.

Conclusion

We recognize and appreciate the value that Part D claims data has to offer in terms of improving the ability to monitor and improve Medicare beneficiaries health as they move between the inpatient and outpatient settings. While this data presents a key opportunity to obtain such a complete picture of what services beneficiaries receive and when, we believe appropriate thought and consideration needs to be given on how to properly handle this information to ensure that the savings obtained in Part D, as well as the privacy of the individuals enrolled in the program continue to be maintained.

Sincerely,



Mark Merritt
President and Chief Executive Officer

DEC 18 2006

December 18, 2006

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-4119-P (Medicare Program; Medicare Part D Data; Proposed Rule)

Dear Administrator Norwalk:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding the use of Part D claims data, published in the Federal Register on October 18, 2006 (the "Proposed Rule"),[1] pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[2] GSK is a world-leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer. GSK fully supports CMS's proposal to make these Part D claims data available for research and public health purposes.

Elderly Americans are a very important and growing segment of the United States population and have high levels of unmet medical needs. Increasingly afflicted with chronic and other debilitating diseases of aging, this group is the largest user of chronic medications. To improve the health status and healthcare of America's seniors, further research is needed in areas of epidemiology, pharmacoviligance and health outcomes. Such research will help to better assess the extent and natural history of specific diseases, improve monitoring of health events and drug safety and track utilization and outcomes associated with pharmaceuticals and other healthcare services. Currently, one of the greatest challenges to conducting research in this area is the lack of a readily accessible research data source that integrates both medical and pharmacy data on a large, nationally representative population aged 65 years and older.

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[1] 71 Fed. Reg. 61445 (Oct. 18, 2006).

[2] GSK also is a member of both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO") and fully supports those associations' comments to the Proposed Rule.

GSK strongly supports CMS efforts to make these Part D claims data more available, and we believe that these data have the potential to help make healthcare more evidence-based. The proposed availability of a Medicare Part D drug database, both on its own and linked to Medicare Parts A and B data, is an exciting development and will provide a research on the epidemiology of aging, chronic diseases, geriatric drug use, treatment effectiveness and drug safety.

We urge CMS to ensure broad access to the Part D claims data for qualified researchers consistent with the agency's current statutory authority regarding the disclosure of Medicare Part A and B data. In addition, while we believe that these Part D claims data offer tremendous opportunities to augment research that contributes to the public health, we also caution CMS with respect to its own proposed uses to recognize the limitations of retrospective claims data.

Also, we encourage CMS to establish a transparent process for reviewing and approving research conducted with these claims data as well as make public government research priorities and activities related to these data. Finally, GSK requests that CMS clarify that confidential financial information will remain protected from disclosure.

Our detailed comments on these issues are set forth below.

I. Access to Part D Claims Data

GSK supports CMS's efforts to make Part D claims data broadly available to qualified researchers for studies furthering public health knowledge. We urge CMS to continue to make Medicare claims data available to researchers in a manner consistent with the agency's statutory authority and that protects patient privacy. Part D claims data will provide researchers with the ability to further knowledge about senior health and to improve healthcare delivery to America's seniors. The potential benefits of these claims data in furthering medical knowledge are far-reaching and include furthering understanding of disease and treatment, pharmacovigilance efforts, improving safety and efficacy of existing therapies, assessing medication adherence, drug/drug interactions and examining the effectiveness of pharmacy services among different types of providers, regional and geographic patterns of care. For this rich data source to be used in a manner that truly furthers public health knowledge, we believe these data should also be available to private sector researchers, who can provide independent analysis and examination. Accordingly, GSK urges CMS to ensure access to the Part D data to qualified researchers in both the government and the private sector.

GSK supports CMS's existing system for permitting access to external researchers through the use of data use agreements (DUAs) that govern the appropriate uses of the data and ensure that patient privacy is protected. The current DUAs used by CMS for the purposes of releasing Part A and B data to external researchers contain strong protection. We encourage CMS to maintain this process while also seeking to improve the efficiency and effectiveness of the existing DUA process to better expedite data access for new research conducted under an existing DUA. GSK believes that many aspects of the existing process work

well, and we encourage CMS to continue its existing DUA policies to help ensure that data are used for high quality research that benefits the public health and that patient privacy is protected. We support the continued review of research protocols and processes to verify that researchers proposing new protocols have the necessary expertise to perform the research in question. We believe that all researchers – whether government or external – should follow the stringent requirements set forth in the existing DUAs.

In the preamble to the Proposed Rule, CMS expressly seeks comments on the "proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health."[3] CMS also asks "whether we should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes or to ensure that proprietary plan data or confidential beneficiary data is not released."[4]

A wide range of researchers and research entities contribute to the knowledge base that improves healthcare and the public health in this country and elsewhere. Pharmaceutical companies, for example, contribute an abundance of critical research as part of drug development and evaluation. Pharmaceutical companies have well-established research centers and invest billions of dollars each year in clinical, safety, health outcome and epidemiological research on the development of medicines that increase both survival and quality of life in a broad range of therapeutic areas. This research and its attendant information greatly contribute to public health knowledge. Researchers in the pharmaceutical sector focus on issues of critical importance to public health by conducting research on the cause of disease, as well as the diagnosis, prevention and treatment with safe and effective medicines.

In particular, the field of pharmacoepidemiology, long recognized for its contributions in safety and regulatory areas, has had a major impact in improving the public's health. This is consistent with the mission of GSK. In 1982, we established our Worldwide Epidemiology Department to bring population-based evidence on disease, treatments and their outcomes to influence decision-making at all phases of a drug product's lifecycle -- from discovery, through development and to medical practice. This epidemiology focus ensures that GSK has all of the disease-based information and population perspectives that are required to identify, develop, and bring to the marketplace safe and effective medicines that address unmet health needs. Our staff of highly skilled epidemiologists and database analysts is among the largest in the pharmaceutical industry, and we have considerable epidemiology expertise and long-established experience in utilizing claims-based and other observational healthcare databases for epidemiology research.

Our Global Clinical Safety & Pharmacovigilance Department works closely with our Worldwide Epidemiology Department to use claims data to investigate safety signals derived from many sources, including literature, clinical trials, regulatory authorities and routine

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[3] 71 Fed. Reg. at 61453.

[4] *Id.*

aggregate analysis of post marketing data. The elderly population is of particular interest due to a higher risk of adverse events due to co-morbidities, concomitant medications and physiologic changes in the elderly, such as decreased renal function. Our Global Health Outcomes Department also works closely with Worldwide Epidemiology to examine the burden of disease, to assess the harm/benefit ratio of a new medicine, to understand the association between adherence, resource utilization and quality of life to drug treatment. Our Applied Outcomes and Analysis group conducts similar studies in a Managed Care context. This group also assesses the impact of prescription benefit designs and disease management initiatives on health outcomes. Therefore, GSK recognizes the value of the Part D data, both on its own and linked to Part A and B data, to support epidemiology, pharmacovigilance and health outcomes research. This type of research is the methodological cornerstone of public health research that aims to improve the health of the general population.

We urge CMS to continue to allow access for external researchers interested in using Medicare claims data for a broad range of critical research studies that have the potential to increase evidence-based knowledge of pharmaceuticals in the context of broader healthcare research questions. Providing for broad access to these data by qualified researchers will encourage a wide range of research studies that together will improve public health knowledge. GSK also urges CMS to clarify its existing policies on release of Medicare claims data to ensure that external researchers have access to this integrated claims data to conduct research on a broad range of studies that further public health. It is critical that CMS provide equal access to the data, while maintaining appropriate safeguards and protection to ensure the confidentiality of the data and appropriate use.

The agency's existing policy on data use agreements provides a solid framework for permitting external researchers to use the Part D claims data. We urge CMS not to impose additional regulatory limitations on private sector researchers. We believe that CMS should narrowly define the "commercial uses" for which it will not release Medicare claims data. We agree that Part D claims data should not be used to target marketing of products to specific health care providers or for marketing to patients. However, we urge CMS not to unnecessarily restrict the many legitimate uses of these data in which researchers, including private sector researchers, may engage. In the interest of public health, we urge CMS to clearly define the limited excluded uses and to permit data inquiries that are designed to answer a broad range of legitimate research questions of benefit to the public health. Numerous publications from administrative claims database research have contributed to the public knowledge base on disease burden, impact of pharmaceutical therapies on hospitalization or other medical resource utilization offset and healthcare delivery in age groups and ethnic population subsets which may be under-represented in clinical trials.

Private sector researchers, including pharmaceutical companies, health plans, pharmacies and private research centers, should be permitted to access this data for legitimate research questions. For example, GSK is currently conducting a SEER-Medicare study to improve our understanding of cardiovascular and other co-morbidities that have a substantial impact on treatment options, treatment response, quality of life and survival for cancer patients. CMS currently permits external researchers, including pharmaceutical manufacturers, to access

such data for public health purposes. We urge CMS to continue to support legitimate research that adheres to scientifically accepted protocols and standards and furthers public health knowledge by clarifying in the final rule that all qualified external researchers will have access to Medicare claims data.

II. Benefits and Limitations of Claims Data

It is critical that Part D claims data is used appropriately and in a manner that is consistent with current research standards. Health-related retrospective claims databases are an important data source for epidemiology and outcomes research. Yet these retrospective databases also pose methodological challenges. An advantage of many retrospective databases is that they allow researchers to examine medical care utilization as it occurs in routine clinical care. They can provide large study populations and longer observation periods, and this allows for the examination of specific subpopulations. Retrospective databases also offer a relatively inexpensive and efficient way to gather information about specific research questions.[5]

These claims data have the potential to improve healthcare quality by helping to address gaps in existing research, examine care delivery systems and shortcomings and further inquiry into pharmaceutical therapies. Specifically, these data can aid studies designed to improve disease understanding and characterize unmet medical needs by evaluating the occurrence, natural history and burden of disease in the elderly population as well as in specific subpopulations. For example, claims data can augment studies on disease incidence, prevalence, patient demographics, patterns of disease progression, comorbidities, disease risk factors, outcomes and trends or forecasts. Claims data also are useful in drug utilization studies designed to assess treatment patterns and the quality of medication use, including research regarding concomitant medications, appropriate dosing, therapy duration and adherence. Other potential uses of claims data in research include:

- Drug effectiveness studies to assess the beneficial effects of disease treatments in clinical practice;
- Drug safety studies to evaluate and quantify background risks and potential risks of medications in actual clinical use, including identifying risk factors for adverse medical events and studies that contribute to planning and evaluating risk management programs to minimize therapeutic risk;
- Studies of new indications to assess opportunities for possible new drug uses and new paths of drug development;
- Health resource utilization studies to assess the health economic benefits of treatments.

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5 *See* Motheral et al, "A Checklist for Retrospective Database Studies – Report of the ISPOR Task Force on Retrospective Databases", Value In Health, Vol. 6 No.2 2003 at 90).

Yet in using research based on retrospective claims data, it will be critical for researchers and policy makers to understand the limitations of these claims data. Clearly, integrated claims data has the potential to assist researchers in many ways. Yet claims data provide only one piece of the information needed to make healthcare decisions and should not be used in isolation without a thorough understanding of the limits of such data. Typically, claims data are not sufficient to make definitive conclusions or coverage decisions. Instead, research based on claims data can be used to augment other research on the specific research question and address gaps in knowledge. It will be important for CMS to recognize the challenges and limitations of claims data as a research tool and to use this research cautiously in informing any coverage or payment decisions.

Retrospective databases – such as one that combines data from Medicare Parts A, B and D – typically are based on medical claims and were collected for a purpose unrelated to the research studies being conducted. As a result, these databases can lack information on some of the variables that may influence the outcome measures being studied. It is particularly important that studies involving this type of claims data be carefully designed, ideally through a rigorous peer review process to ensure that the data analysis plan was developed appropriately. For example, a patient likely receives a particular medication due in part to the patient's clinical characteristics, including their primary diagnosis and any comorbidities, as well as physician prescribing practices. The database may not contain complete information on both of these components, however, and this can lead to biased estimates. Researchers must design their studies to account for such possible biases. It also is critical that a study be designed in a manner that accounts for the effects of all variables that have an important influence on the outcomes being studied in order to avoid biased estimates of treatment effects. Study designs should control for comorbidities and disease severity using commonly accepted risk adjustment techniques that are appropriate for the Medicare population and the disease being studied.

In addition to urging caution in the utilization of research based on retrospective claims data, GSK urges CMS to ensure that all researchers who utilize these data be held to high methodological and ethical standards. Certainly GSK, as a commercial entity, abides by these standards. In particular, a document that may be helpful is the "International Society for Pharmacoeconomics and Outcomes Research's (ISPOR) Checklist for Retrospective Database Studies." We support CMS's goal of ensuring high quality research, and we believe that accomplishing this goal requires both an awareness of the possible limitations of retrospective data research as well as consistent methodological standards among researchers.

III. Transparency of the Process for Reviewing and Approving Research Studies

We request that CMS make available information on the number of external requests it receives for Medicare claims data and the manner in which the agency responds to these requests, such as how research requests are prioritized, the timeliness of the approval process, and the amounts of any fees charged for various types of data. We also believe that the publication of government-generated reports and analyses would be useful, as well as a description of the federal priorities for use of government sponsored research using Medicare

claims data, much as the Agency for Healthcare Research and Quality (AHRQ), regularly publishes its proposed research priorities and seeks public input on those priorities. This transparency will help to ensure that all stakeholders can participate in a public dialogue regarding research priorities. GSK also requests that when analyses of claims data are publicly released or used as part of a public policy decision-making process that the research protocols, analysis plans and data sources used also are made public. This will allow other researchers to replicate and validate the research and will help to place the research in the most appropriate context.

We urge CMS to establish an open and transparent process to allow for external verification and replication of research analyses. This will be particularly critical when claims data is being used to inform coverage or payment decisions for particular items or services.

IV. Protection of Confidential Financial Information

In the Proposed Rule, CMS explains its statutory authority to collect this Part D claims data for purposes not related to payment under Section 1860D-12 of the Social Security Act. CMS sets forth the analysis that the agency has the authority to collect data from Part D plans that the agency finds necessary and appropriate. Under Section 1860D-12, CMS may, through its contracting requirements with Part D plans, collect data without adhering to the restrictions of the data collected under Section 1860D-15, which the agency may use only for payment purposes. In the preamble to the Proposed Rule, CMS also states that this analysis does not affect the applicability of the Trade Secrets Act.[6] We request that CMS clarify that this Section 1860D-12 authority does not permit CMS to override the disclosure limitations found elsewhere in the Part D statute relating to the disclosure of confidential rebate information protected by the Trade Secrets Act or by § 1927 of the Medicaid statute. Section 1927(b)(3)(D) of the Social Security Act expressly protects rebate information that Part D plans must disclose to the Secretary pursuant to § 1860D-2(d)(2) as well as information that Part D plans are required to disclose to the Secretary regarding the amount of fees paid to providers of a plan's medication therapy management programs. We urge CMS to clarify in the final rule that its § 1860D-12 authority does not undermine these § 1927(b)(2)(D) protections of this confidential financial information. The Part D claims data that CMS is proposing to collect and disclose under the Proposed Rule is based on patient-level claims and is distinct from competitively sensitive financial data regarding rebates.

V. Conclusion

As CMS prepares the final rule, we ask the agency to remain focused on the statute's greater purpose: to provide Medicare beneficiaries with important drug therapies in clinically appropriate and cost-effective settings. Patients' access to advanced therapies depends in part on the availability of high quality healthcare research, and the Part D claims data provides

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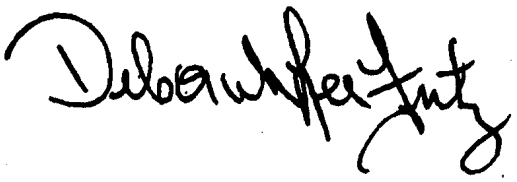
[6] *See* 71 Fed. Reg. at 61453.

an opportunity for greater outcomes research opportunities. By linking the Part D data to the Part A and B claims data, researchers will have a greatly increased ability to conduct safety, pharmacoepidemiologic, economic and outcome studies relating to prescription drugs. In turn, this research will benefit the health of America's seniors. GSK strongly supports the appropriate use of Medicare claims data to reinforce a broad, disease-centered research agenda and to promote quality improvements in the healthcare delivery system. This will allow practitioners to provide more evidence-based care to patients and will help further the development of increasingly effective ways of providing critical healthcare to Medicare patients.

GSK appreciates the opportunity to comment on the issues we have identified in this letter, and we look forward to a final rule that furthers the goal of ensuring Medicare beneficiaries meaningful access to vital drug therapies by increasing the scope of research that is available to inform effective identification and treatment of diseases. Please feel free to contact me at (919) 483-2191 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Deborah L. Fritz, Ph.D., MPH
Director, Policy and Healthcare Standards
GlaxoSmithKline

Thomas J. Sabatino, Jr.
Executive Vice President
and General Counsel

DEC 18 2006

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Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530 USA
Phone +1 908 298 7367
Fax +1 908 298 7555
thomas.sabatino@spcorp.com

Schering-Plough

December 18, 2006

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4119-P: Medicare Program; Medicare Part D Data

On behalf of Schering-Plough Corporation, I appreciate this opportunity to provide comments on CMS-4119-P, *Medicare Program; Medicare Part D Data*. Schering-Plough is a global science-based health care company with leading prescription, consumer and animal health products headquartered in Kenilworth, NJ. Through internal research and collaborations with partners, Schering-Plough's 30,000 employees discover, develop, manufacture and market advanced drug therapies to meet important medical needs.

Schering-Plough believes that the Medicare prescription drug benefit (Medicare Part D) offers an important new source of data for the federal government and other stakeholders. We support CMS' efforts to make the data available for high quality research, with appropriate protections for confidential information.

Our comments address the confidentiality of identifiable and proprietary data, as well as two issues for which CMS requests comments in Section II.C., *Sharing Data With Entities Outside of CMS*, of the proposed rule:

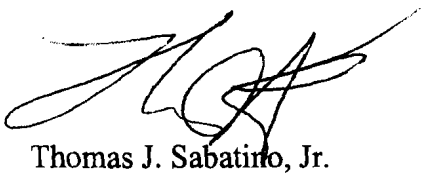
- Proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health.

- Need for additional regulatory limits beyond existing data use agreement protocols for external researchers to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.

In particular, we suggest that CMS implement a public process for posting and evaluating data requests to ensure that analyses using the Part D data are scientifically valid and adequately protect the confidential information contained in the data set. Our comments provide specific recommendations, drawn from existing CMS processes, to achieve these objectives.

If you have questions or if you need additional information, please contact Jenifer Levinson at 202-463-7372 or jenifer.levinson@spcorp.com.

Sincerely,



Thomas J. Sabatino, Jr.
Executive Vice President
and General Counsel

Comments on Sections II.A: Information to be Collected and Section II.B: Purpose of CMS Collecting Information

We support CMS' proposal to use the claims data already collected from Part D plans under section 1860D-15 of the Act, rather than requiring new data collection, as described in Section II.A of the proposed rule. Using data already being submitted will streamline the process and will minimize the data collection burden on Part D plans and on CMS, and the 37 data elements currently collected provide a rich source of information for program administration and research purposes.

However, in Section II.B of the proposed rule, CMS proposes to add new language (as §423.505(f)(3)) requiring Part D plans to provide "...access to drug claims and related information that is already submitted to CMS for purposes the Secretary deems necessary and appropriate." It is unclear from this language what additional information CMS anticipates using, other than the 37 data elements included in the Prescription Drug Event (PDE) data, described in Section II.A of the proposed rule. It is also unclear whether data beyond the 37 data elements in the PDE data would be shared with other government or non-government entities.

We ask that CMS clarify its intentions regarding collecting and using any data beyond the 37 data elements plans submit as part of the PDE data, particularly regarding confidential and proprietary data elements. As CMS notes in Section II.F of the proposed rule, sharing of Part D data is subject to existing law that protects confidential information, including the Privacy Act and the Trade Secrets Act. CMS specifically discusses the applicability of these laws to certain Part D data elements in Chapter 9 of the Medicare Part D Manual:

> The Freedom of Information Act (FOIA) is codified at 5 U.S.C. §552. Its basic purpose is to promote the continued existence of an informed citizenry. More generally, FOIA makes information collected by government agencies available to the public. **Consistent with our approach under the Part C program, CMS will not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans or their first tier entities, downstream entities, or related entities.** [Emphasis added.]

We agree with CMS that these privacy laws apply to the Part D data and request that CMS clarify that the specific Part D data elements protected under these acts will not be made available to other government and non-government entities under this rule. We request that CMS clarify that the rebate and discounting information submitted to CMS by Part D plans will not be disclosed pursuant to this rule and that nothing in this rule shall be deemed to affect or otherwise modify the confidentiality protections afforded by any other Federal law or regulation.

SCHERING-PLOUGH CORPORATION
COMMENTS ON CMS 4119-P:
MEDICARE PROGRAM; MEDICARE PART D DATA

Comments on Section II.C: Sharing Data with Entities Outside of CMS

The Medicare prescription drug program offers a rich new source of information for government and external researchers. The ability to link prescription drug data to existing claims data sets for Parts A and B further enhances the value of these data and expands their potential for research.

However, the rich potential of these data also poses certain risks. First, the data are complex. Understanding the meaning of each data element and appropriate analytic uses of these data, developing valid methodologies for analyzing the data, and developing valid approaches for linking the Part D data with other data sets requires significant research skill and experience. Given the importance and sensitivity of the Part D data, erroneous methodology, incomplete understanding of the data elements, or inadequate security could have significant implications in terms of circulating erroneous conclusions regarding health outcomes and breaching patient privacy.

The methodological limitations of claims data for outcomes research have been widely documented in the literature, as have the complexities of linking claims data sets.[1,2,3,4,5,6,7] Some of the key methodological issues include the challenges in determining the relationship between exposures and outcomes as claims represent point in time events that may be proxies for the clinical decision pathway (a rule-out diagnosis appears as a coded definitive diagnosis). Claims data that include linked pharmacy data can produce substantive and critical limitations in assessing confounding by underlying disease severity, confounding by indication, and lack of data on which to account for the case mix of patients. These issues alone can significantly limit the validity of comparative analyses. The critical underlying concern is the degree to which claims analyses really reflect associations and not causal relationships, a point that often eludes those inexperienced in analyzing and interpreting these data.

In addition to methodological concerns, the privacy issues inherent in the public use of identifiable data files are even more acute for the Part D data CMS proposes to release. The Part D data include confidential information on beneficiary income, cost sharing, health status, and utilization, as well as proprietary financial information regarding health plan, pharmacy, and prescription drug costs.

While the risks of public use of the Part D claims data set are significant, the benefits in terms of understanding issues related to patient outcomes, safety and quality warrant the data's release to qualified researchers within and outside of the government. However, given the unique risks posed by the Part D data set, particularly when linked with other available data sets, we suggest that CMS implement more comprehensive guidelines and protections for use of the data.

Our specific comments on these issues are structured to address two issues on which CMS solicited comment in the proposed rule:

- Proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health.

- Need for additional regulatory limits beyond existing data use agreement protocols for external researchers to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.

Limitations on Data When Shared for Purposes other than Fulfilling CMS' Responsibility to Administer the Part D program

As CMS notes in the proposed rule, there are a number of important potential uses of the Part D data that will serve the public health and safety. However, as discussed above, there are also risks of the data being used improperly. To ensure appropriate use of the data, CMS should apply the following principles to all requests to use the Part D data for purposes other than CMS's administration of the Part D program.

- The request should be for a legitimate and clearly defined research purpose. CMS should require that requestors of the data submit a specific research proposal that outlines the data elements needed, the proposed methodology for the analysis, and the intended use of the analysis.

- The data should be made available to any qualified researcher that wishes to utilize the claims data for a legitimate research purpose. Legitimate research requests can come from a range of government and private entities, including other government agencies, non-profit research groups, academic researchers, health plans, providers and provider groups, pharmaceutical manufacturers, and others. Many different stakeholders, including commercial entities, have an interest in and the capability of conducting high-quality outcomes and safety research using the Part D data, including analyses of compliance with drug therapy, drug-drug interactions, and appropriate prescribing for the over-65 population. Therefore, CMS should focus on the intended use of the data, not the organization making the request.

- Only the specific data elements needed for the requested research should be released. Given the highly sensitive nature of the data and per widely accepted data privacy standards, CMS should release only the data elements needed to conduct the proposed research. As noted above, requestors of the Part D data should be required to specify to CMS which of the Part D data elements they need to perform their proposed research.

- Requests to use the Part D data should be made public. To ensure accountability to the principles outlined above, CMS should make public all requests to use the Part D data. Specific recommendations regarding establishing a public process are discussed below.

We believe these principles would address the concerns that CMS discussed in the proposed rule regarding use of the Part D data for commercial purposes. To further address that concern, we recommend that CMS provide additional information regarding the types of studies and uses of the data that CMS considers commercial. Providing additional clarification on the types of studies considered to be for commercial purposes would provide potential requestors of the data with ground rules before they submit requests, thereby reducing the number of inappropriate requests that CMS must review.

Need for Regulatory Limits for External Researchers

The current data use agreement procedures provide a good foundation for ensuring that research using the Part D data is appropriate, accurate, and maintains the security of confidential information. However, for the reasons discussed above, we feel that the current process needs to be enhanced for the Part D data.

We recommend that CMS implement a public process for posting and responding to requests to use the Part D data. To minimize the burden on CMS of implementing a new process, our recommendations are based on existing CMS processes for review of and comment on Part D formulary guidance documents, Medicare National Coverage Determinations and coverage guidance documents. The process also is similar to the requirements for registering clinical trials in the ClinicalTrials.gov directory.

Specific recommendations regarding how CMS should structure the process are as follows:

- Require that all data requests include the following elements: (1) identity and qualifications of the researchers who would be conducting the study, (2) any organizations with which the researchers are affiliated or on behalf of which they are conducting the research, (3) expected timing of the analysis, (4) protocols that would be used to protect confidential information, and (5) the intentions of the requestor in terms of dissemination of results (peer-reviewed or other publication, guidelines development, health plan coverage decisions, etc.). CMS should require more detailed information on research methodology and data sources for analyses that are intended to be released to the public or that will be used in public policy decisions. Several of these elements are already included in CMS' existing data use agreement, and these requirements should not represent a significant increase in effort for CMS in terms of reviewing data requests.

- Post a brief summary of the data requests, including principle investigator(s), study objectives, study timing, and intentions for dissemination, on a publicly accessible location on the CMS website. To minimize the administrative burden on CMS, CMS could require that requestors of the data provide this summary. CMS should also create an online mechanism for submitting and posting public comment on the research requests while the requests are still under review by CMS, and CMS should consider these comments when reviewing the data requests.

- CMS decisions on the data requests should be posted on the website, including the rationale for granting (or not granting) the request. Should CMS determine that revisions to the data request proposal are needed before the request can be approved, this information would also be posted on the website. CMS should review and post decisions on all data requests within 45 days of receipt of a complete request.

Permitting public comment will provide CMS with additional information from experts on methodology, privacy, and appropriate uses of the Part D data, which will supplement CMS' internal analysis of the requests. Posting the decision rationales will ensure that requestors are well informed of CMS' requirements for using the Part D data and should improve the quality of data request submissions. Moreover, the posting will create public accountability for users of the Part D data and will help ensure data are used and reported appropriately, similar to the purpose of the ClinicalTrials.gov database. Finally, the specific timelines for comment and decision-making will ensure that important research using the Part D data can begin in a timely manner.

Applying a consistent process for all requests to use the Part D data is the best approach to ensure proper use of the data and to protect confidentiality. Therefore, we recommend that this process be widely applied to data requests from any non-governmental organization or individual, including academic researchers, patient and provider groups, foundations, and commercial entities.

CMS also should establish a process for informing the public about government research using the Part D data. We recommend that CMS provide public reports, on at least a quarterly basis, of the analyses that have been generated by government agencies using integrated claims data provided by CMS. We recommend that CMS also post any public policy decisions made by CMS or other government agencies (e.g., Medicare coverage and reimbursement decisions, FDA reviews, etc.) based on analysis of the Part D data.

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