CMS DATA AND PRICE INFORMATION COLLECTION: What are the Implications?

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CMS' GOALS
(as stated on website)

- Protect and improve beneficiary health and satisfaction.
- Foster appropriate and predictable payments and high quality care.
- Promote understanding of CMS programs among beneficiaries, the health care community, and the public.
- Promote the fiscal integrity of CMS programs and be an accountable steward of public funds.
- Foster excellence in the design and administration of CMS programs.
- Provide leadership in the broader health care marketplace to improve health.

CMS as "Public Health Agency"

- CMS Quality Improvement Roadmap
- "CMS is focusing on these opportunities because its size and broad impact make it a public health agency"
- Various initiatives on evidence reflect this transformation
  - Examples include Coverage with Evidence Development, Integrated Data Strategy

NEW OPPORTUNITIES FOR DRUG INFORMATION COLLECTION

- Expansion of Medicare Coverage Part D – 2006
- Coverage with Evidence Development (CED)

PART D – A New Program and a New Model

- Basics on Part D and Data Information Flow
  - Part D is administered by private plans
  - Part D plans arrange pharmacy networks, develop formularies, enroll beneficiaries, pay claims
  - Plans bid each year and bid includes premium amount, benefit design, formulary
  - Plans submit data in order to obtain payment and for general oversight
  - Plans are at financial risk for the benefit, but not full risk

PART D: BASIC BENEFIT DESIGN

- $250 Deductible
- 25% cost sharing up initial coverage limit
- 100% cost sharing in coverage gap until spending reaches catastrophic coverage threshold
- Catastrophic Coverage – greater of $2/$5 copay or 5% coinsurance

PART D – Government Payments

- Premium subsidy payment - 74.5% subsidy
- Reinsurance – 80% of allowable reinsurance costs after catastrophic coverage threshold triggered
- Risk Corridor Payment
- Low income subsidy

INFORMATION REQUESTED FROM PLANS

- Prescription Drug Event Data – Specific information, including claims data
- Part D Plan Reporting Requirements – Statistical information and specific information, including specific rebate reporting

PART D PLANS – Prescription Drug Event (PDE) Data – April 12, 2005

- As a condition of payment, plans must submit data and information. CMS uses the data:
  - To reconcile low income cost sharing subsidy and reinsurance
  - To implement risk sharing through risk corridor payments
  - So drug utilization data may be added to risk adjustment model for direct subsidy
  - To verify plan administration of True Out of Pocket (TrOOP) Expenses – (expenses incurred by or on behalf of enrollees in cost sharing and coverage gap in order to reach catastrophic coverage)
  - Program oversight and program integrity

PDE INFORMATION - Key Fields to Uniquely Identify PDE Record

- Health insurance claim number (HICN) – basic beneficiary identifier in Medicare Program
- Service Provider identifier
- Prescription/Service reference number
- Date of Service (when prescription is filled)
- Fill Number – original vs. refill prescription

PDE INFORMATION - Other Prescription Related Information

- Patient date of birth and gender
- Paid Date
- Product/Service ID-NDC code
- Compounding code
- DAW/Product selection code – generic substitution instructions or dispense as written
- Quantity dispensed
- Day supply
- Drug Coverage Status Code (whether covered under Part D or not or by PDP)
- Out of Network code
- Catastrophic Coverage Code

PDE INFORMATION – Costs that Qualify for Payment

- Ingredient Cost Paid – the amount the plan paid the pharmacy for the drug
- Dispensing fee paid
- Amount attributed to sales tax
- Gross drug costs below out of pocket threshold
- Gross drug costs above out of pocket threshold
- Patient pay amount (not reimbursed by third party)
- Other TrOOP amount (qualified payments by third parties that count toward TrOOP)

PDE – OTHER INFORMATION

- Low Income cost sharing subsidy amount
- Patient liability reduction due to other Payor Amount
- Covered plan paid amount
- Non-covered plan paid amount

PART D PLAN REPORTING REQUIREMENTS

- Rebate reporting requirement
- Rebates summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations or combinations
- All other price concessions, including discounts, value adds such as gift-in kind or other programs (e.g., coupon or disease management programs specific to a Part D sponsor) are reported separately
- Note: Negotiated Prices available to enrollee are required to take into account rebates, discounts and other price concessions but do not necessarily have to reflect all manufacturer price concessions
- According to CMS, manufacturer rebate may be used in negotiated prices, to lower premiums or deductibles or fill in the gap

OTHER PART D REPORTING REQUIREMENTS

- Enrollment/Disenrollment
- Reversals
- Medication Therapy Management Programs
- Generic Dispensing Rate
- Grievances
- P&T committee
- Transition
- Prior Authorization, Step Audits, Non-Formulary exceptions
- Tier Exceptions
- Appeals
- Call Center Measures
- Overpayments
- Pharmaceutical Manufacturer rebates, discounts, and other price concessions
- Pharmaceutical Manufacturer Access/Performance Rebates Received by Pharmacies
- Licensure & Solvency, Business transactions, financial requirements
- Drug Benefit Analysis

HHS MOVING MEDICAL INNOVATIONS FORWARD – New Initiatives from HHS (January 2005)

- Collaboration between FDA and CMS includes
  - Parallel Review at the request of the applicant
  - Humanitarian device exemptions
  - Summaries of Safety and Effectiveness
  - Post market surveillance data-collection of new Part D information could provide FDA, CMS, industry and the public with invaluable information regarding the use of medical products and safety, effectiveness and the safety and effectiveness of off-label use.

CMS MEDICARE PRESCRIPTION DRUG DATA STRATEGY

- Announced in April 2005
- Improving Evidence for Patient Care Through the Medicare Prescription Drug Benefit

CMS MEDICARE PRESCRIPTION DRUG DATA STRATEGY

Part D electronic systems will help provide:

"better evidence on the experience of people with Medicare in using medications, including better information on unusual events and on the impact of drugs on avoiding disease complications and their associated cost. With better evidence, doctors and patients can get greater benefits from Medicare drug coverage, while reducing the overall costs on health care."

CMS MEDICARE PRESCRIPTION DRUG DATA STRATEGY

- New opportunities for CMS to learn
  - Drug utilization patterns and adverse events
  - Avoidance of disease complications
  - Consequences for other Medicare costs that are associated with different ways drug might be used by Medicare beneficiaries
- Information could add to evidence developed through existing prospective research studies, including randomized controlled trials, registries and other clinical studies.
- Acknowledges limitations and opportunities.

CMS MEDICARE PRESCRIPTION DRUG DATA STRATEGY

- Public-private partnership
- Evidence on important questions on the use, risks, and benefits of certain drug therapies can be developed by linking relevant Part D data to hospital, physician, and other medical utilization data (Medicare Part A and B data).
- Evidence could be developed as part of "collaborative efforts for improved post-market surveillance of FDA-approved drugs and devices".
- Evidence could be developed about drug use in a broader range of conditions, including more detailed evidence on particular types of patients, including off-label uses.
- Evidence could be developed on the effect of formularies and other features of drug coverage and beneficiary support programs on the outcomes and overall costs of care.
- PBM data on patients under 65 could complement Medicare claims data.

COVERAGE WITH EVIDENCE DEVELOPMENT INITIATIVE

- January 2005 National Coverage Determination (NCD) for Anticancer Therapies for colorectal cancer for certain products in clinical trials sponsored by NCI
- January 2005 NCD for Implantable Defibrillators requiring registry maintenance; ICD registry requires collection of patient identifying information, certain history and clinical characteristics, medications, facility and provider information, ICD indicators, device information, in-hospital complications
- April 7, 2005: CMS released Draft Guidance on Factors CMS Considers in Making a Determination of Coverage with Evidence Development (CED Guidance)
- July 14, 2005: CMS issued a fact sheet with Q&A on responses to stakeholder feedback. 65 organizations filed comments.
- July 12, 2006: CMS issued Guidance on National Coverage Determinations with Data Collection as a condition of coverage.

CED GUIDANCE WHAT IS THIS?

- The purpose of CED is to "generate data on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service."
- Section 731 of MMA required CMS to issue factors considered in making NCDs of whether an item or services is reasonable and necessary based on FDA's good guidance practices.

CMS GOALS IN DRAFT CED GUIDANCE

- Linking coverage with evidence development potential to improve health outcomes
- CED will enable coverage to be provided where insufficient data
- Linkage of coverage to data collection ensures care is reasonable and necessary

REVISED CED GUIDANCE – 2 Approaches to CED

- Coverage with Appropriateness Determination (CAD) – registries required
- Coverage with Study Participation (CSP) – research setting required

REVISED CED GUIDANCE – CAD Used:

- If the item or service should be restricted to patients with specific conditions and criteria.
- If uses of the item or service should be restricted to providers with specific credentials or training.
- If a concern exists among clinical thought leaders that substantial opportunities exist for misuse of the item or service
- If the coverage determination significantly changes how providers manage patients utilizing the item or service.

REVISED CED GUIDANCE – CED Registry Requirements

- Qualified scientific oversight
- Tested and validated data collection methods
- Adequate patient safety and monitoring
- Quality assurance and data protection
- Appropriate human subjects protection

REVISED CED GUIDANCE – CSP Uses Include:

- When available evidence might not include outcomes relevant to Medicare beneficiaries
- Available research did not adequately address risks and benefits of off-label and other anticipated uses of a drug, biologic, device or service
- Available research may not include patient types prevalent in Medicare
- Insufficient published research to support a reasonable and necessary determination

ACCESS TO CMS' DATA – Proposal Required

- Describes how the project will improve the quality of care for Medicare beneficiaries or the administration of the Medicare program
- Provides literature review
- Describes the methods with definitions of outcomes, files, and variables needed
- Provides an analytic plan
- Describes the human subjects to be applied, if relevant
- Lists the qualifications of key personnel
- Provides a work plan and a dissemination plan
- Includes a provision for final report to CMS

ACCESS TO CMS' CED DATA – Data Use Agreement

- Identity of custodian of data
- Declaration that the protocol is accurate
- Prohibits sale or granting access to data without authorization
- Defines termination date

CMS COLLECTION OF PRICE DATA

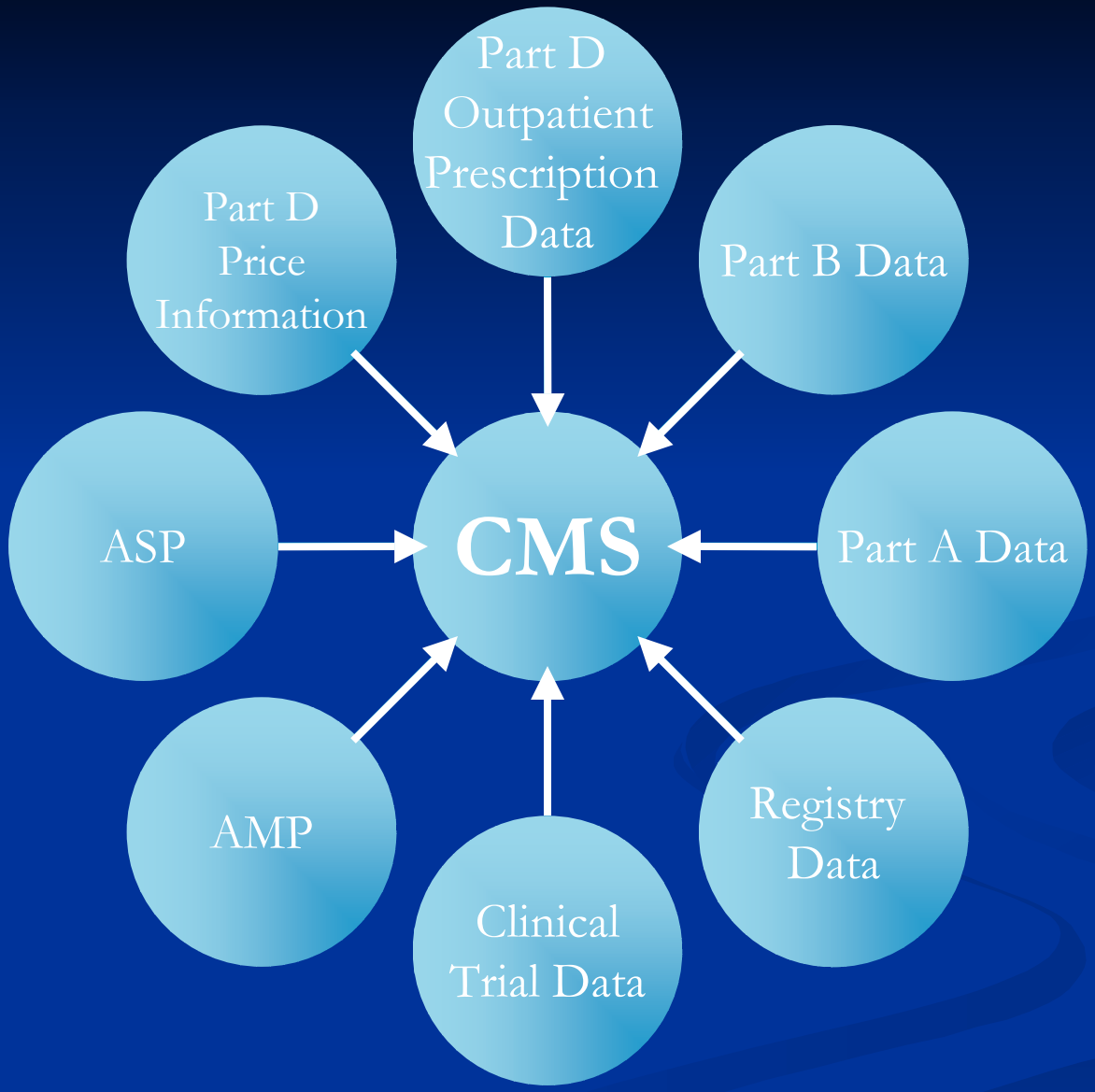
- Medicare Part D – Outpatient prescription drugs
  - Negotiated Price Data
  - Rebate and other price concession data
  - Cost data
- Medicare Part D - Confidentiality
  - Negotiated Prices on Plan Finder Website
  - Other data confidential

CMS COLLECTION OF PRICE DATA

- Medicare Part B
  - Average Sales Price (ASP) which is the manufacturers' sales to all purchasers (with certain exemptions), net of discounts, divided by the total number of units of such drug or biological sold by the manufacturer during the quarter
  - ASP is reported but not actual sales data not reported
  - ASP data is kept confidential

CMS COLLECTION OF PRICE DATA

- Medicaid
  - Average Manufacturer Price (AMP) – the average price paid to manufacturers by wholesalers for the retail class of trade. After January 1, 2007 under Deficit Reduction Act of 2005 (DRA), prompt pay discounts will be removed from calculation.
  - AMP and Best Price are reported quarterly
  - Under DRA, separate reporting of prompt pay discounts
  - Under DRA, separate reporting of nominal prices
  - Actual sales data not reported
  - DRA requires CMS to post AMPs on a website


Part D Outpatient Prescription Data
Part D Price Information
Part B Data
ASP
CMS
Part A Data
AMP
Registry Data
Clinical Trial Data