January 15, 2009

Report to Congress: Information on the Competitive Acquisition Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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EXECUTIVE SUMMARY

Section 303(d)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; Pub. L. 108-173) introduced a Competitive Acquisition Program (CAP) for selected outpatient drugs and biologicals covered under Medicare Part B. Under this program, Medicare chooses drug supply vendors through a competitive bidding process. Physicians may elect to participate in the program annually, in which case they obtain selected Part B drugs through a CAP vendor. In late 2005, the Centers for Medicare & Medicaid Services (CMS) conducted the first round of bidding for approved CAP vendors. Physicians were first able to acquire drugs through the CAP on July 1, 2006. This Report to Congress examines the effects of the CAP on the range of vendor choices available to physicians; drug prices realized under CAP versus usual Part B drug payments; programmatic savings; reductions in cost-sharing; beneficiary satisfaction; access to competitively biddable drugs and biologicals; and satisfaction among participating physicians. This report is based on experience realized under the first six months of the program. Data collection for this report is during the early phases of a new program that is changing and undergoing various refinements.

Background on Medicare Part B Drugs

Prescription drugs covered by Medicare Part B generally include drugs administered "incident to" a professional service, drugs administered through durable medical equipment (DME), and certain drugs covered by statute. A variety of drugs are covered under Part B, for example: anticancer (chemotherapy) drugs; drugs for diseases such as rheumatoid arthritis and Crohn's disease; nebulized drugs for patients with COPD and asthma; some vaccines; clotting factors; blood products; and IV immunoglobulins for immunocompromised patients. For the subset of drugs that are covered under the "incident to" provision, the cost of the drug must represent a real cost to the physician; a physician generally cannot bill Medicare and the beneficiary for drugs purchased by another entity (e.g., a hospital, a pharmacy, etc).

Medicare Part B drugs can be administered on an outpatient basis in a variety of settings and locations, such as professional offices, hospital outpatient departments (HOPDs), freestanding clinics, and beneficiaries' homes, and the amount paid by Medicare (and by the beneficiary as co-insurance) for these drugs depends critically on where the drug is administered. For example, HOPDs (under the Hospital Outpatient Prospective Payment System) are paid separately for only a selected set of Part B-covered drugs. In contrast, physicians, suppliers, and DME suppliers receive separate payment for the vast majority of Part B drugs they administer (in addition to being paid the professional fee for administering the drug). All Part B drug payments are subject to Local and National Coverage Determinations (LCDs and NCDs).[1]

Beginning in 1992, payment limits for Part B drugs were based on the lower of 100 percent of the average wholesale price (AWP) or the estimated acquisition cost (EAC). This policy was implemented through the use of the list AWP, a commercially-published list price that may not reflect actual prices paid to wholesalers after various kinds of discounts. Under the Balanced Budget Act of 1997 (BBA; Pub. L. 105-33), drugs not paid on a cost or prospective

1 Medicare Carriers and Program Safeguard Contractors are required to apply all LCDs and NCDs to all claims for drugs acquired through the CAP and to all drug administration services.

payment basis were paid based on the lower of the actual charge or 95 percent of AWP. Through rulemaking, CMS based payments for drugs with generic versions available on 95 percent of the lower of the median AWP for all generic forms or the lowest brand-name AWP. For payments in 2004, the MMA revised the payment limits for drugs not paid on a cost or prospective payment basis to the lower of 85 percent of AWP, with certain drugs having statutory exceptions to this revised payment methodology.

In part to compensate for the reduction in payment rates for Part B drugs mandated by the MMA beginning in 2004, and to respond to criticism that higher payment rates for drugs were necessary to offset inadequate payments for administration, drug administration service fees under the Medicare Physician Fee Schedule (MFS) were increased between nine and 459 percent, depending on the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code used for billing for drug administration, including a 32 percent one-year transition adjustment.[2] Specifically, Section 303(a) of the MMA required CMS to provide Work Relative Value Units (RVUs) for drug administration services and also to provide a "transition adjustment" in payment for these services of 32 percent in 2004 and three percent in 2005.[3] Although the MFS changes were designed to fully compensate for drug payment amount reductions, some physician groups, particularly oncologists/hematologists, have denied that parity was achieved. According to press reports, some have reduced the scope of their oncology services or referred patients to hospitals for chemotherapy treatments.

Section 303(c) of the MMA, amending Title XVIII of the Social Security Act by adding Section 1847A, required that payment for the vast majority of physician-administered Part B drugs be based on the Average Sales Price (ASP) for each drug, beginning in January 2005. The average sales prices, reported quarterly by drug manufacturers, are the average prices paid for each Part B drug by all purchasers, net of any discounts.[4] The ASP is based on the manufacturer's average price per unit as represented by the 11-digit National Drug Code (NDC) for all sales excluding certain sales exempted by statute. Exceptions to the ASP-based pricing methodology are possible under MMA if the Office of the Inspector General studies indicate that the widely available market price or average manufacturer price for a drug or biological exceed the ASP for that drug or biological.

Although the conversion to ASP based pricing was a significant change in Medicare *payment* for these drugs, it did not significantly change the *method* by which physicians acquire drugs. Physicians receiving payment under Section 1847A of the Social Security Act still "buy and bill" for Part B drugs they administer.

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2 See Table 10 in the Medicare Physician Fee Schedule Interim Final Rule for Calendar Year 2004 (69FR1108), reprinted in Section 1 of this report, for details.

3 Prior to this change, these drug administration codes did not have Work RVUs associated with them.

4 Subsequent CMS regulations have clarified that purchases of Part B drugs by vendors selected to provide drugs under the Competitive Acquisition Program for Part B Drugs are excluded from ASP computations.

The Competitive Acquisition Program

Another MMA mandated Part B-covered drug payment reform—and the focus of this evaluation—is the introduction of physician acquisition of certain Part B drugs through the CAP. Under this program, CAP-participating physicians would submit an order for a drug prior to the patient's visit from a vendor selected by CMS through a competitive acquisition process. After the physician administered the drug, the physician would submit a claim for the drug administration procedure, but not for the drug itself. However, the physician would indicate the drug on the claim, along with the order number. The vendor providing the drug would bill the beneficiary and the Medicare program for the drug.

To begin the process of CAP implementation, the Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rulemaking (NPRM) for the CAP program on March 4, 2005. This NPRM laid out a number of fundamental design decisions for the CAP program for which CMS solicited public comment. Subsequently, further interim final and final rules were released as necessary in response to public comments, legislative changes, and other circumstances.

As outlined in the March 2005 NPRM, CMS proposed that drugs eligible for inclusion in the CAP consist of drugs administered incident to a physician's service and described in Section 1842(o)(1)(C) of the Social Security Act. CMS also specifically proposed to exclude blood products, vaccines, drugs infused through DME, and drugs usually dispensed by pharmacies (e.g., oral immunosuppressive drugs). Further, under the MMA statute, the Secretary has the authority to exclude from the programmatic group any drugs and biologicals whose inclusion is unlikely to result in cost savings or whose inclusion would have an adverse effect on access. Regarding the drugs included in the initial round of CAP bidding, CMS initially selected a set of 169 Part B drug HCPCS codes (out of more than 500), representing approximately 85 percent of allowed charges for physicians' Part B drugs that satisfied a set of criteria. Medicare Part B-covered vaccines, drugs infused through a covered item of durable medical equipment, and blood and blood products were excluded due to statutory restriction. Further, several other classes of drugs were excluded using statutory authority: erythropoietin administered to ESRD patients; intravenous immune globulins; oral anti-emetic and anti-cancer drugs; controlled (Schedules II, III, IV, and V) substances; clotting factors; tissue; low volume drugs (with less than $1 million in allowed charges in office settings in 2004 or $250,000 for anti-infectives, antidotes, and cardiovascular agents); and unclassified/not otherwise classified (NOC) drugs.[5] Certain other specific drugs, including specific forms of leuprolide, were also excluded.

The final set of drug HCPCS codes for initial bidding was drawn from the set of drugs remaining after the above exclusions were applied. First, drugs determined to be most often administered by oncology specialties (hematology, hematology/oncology, medical oncology, surgical oncology, urology, and gynecology/oncology)—oncolytics, chemotherapy adjuncts, anti-emetics, and hematologics—were included in an interim list. In addition, drugs used relatively often (appearing on at least one percent of Part B drug-containing claims) by ophthalmologists, psychiatrists (including addiction medicine and neuropsychiatry), and

5 NOC drugs could be added later to the CAP on a case-by-case basis. They were excluded from bidding because of the lack of claims data necessary for computing bidding weights.

rheumatologists, were also included.[6] A total of 169 HCPCS codes were identified using this procedure, and bidding weights were computed based on relative volume. These drug HCPCS codes are the "weighted drugs." At the time, under the assumption that CAP payment amounts for these drugs would equal 106 percent of ASP, about 38 percent of CAP payments would be for cancer chemotherapy; 35 percent for hematologics, mostly for the hematopoietic drugs epoetin alfa and darbepoetin alfa; and eight percent for immunomodulators, mostly for infliximab (used for rheumatoid arthritis, Crohn's disease, ulcerative colitis, and plaque psoriasis).

In addition to the weighted drug list, CMS added a set of drugs with HCPCS codes assigned in 2005; these drug HCPCS had no Medicare volume in 2004 (used in the CAP drug selection criteria described above). After adding these new drugs, and making other adjustments for changes in HCPCS coding, for 2006, a total of 182 Part B drugs were included in the CAP to be provided by the CAP vendor.

Physician participation in the CAP is voluntary. Physicians who elect to participate in the CAP must generally, with some allowable exceptions, acquire drugs covered by the CAP from a vendor selected by the CMS through the competitive bidding program. Under this method, participating physicians submit an order to the vendor, and the vendor then ships the drug to the physician. By statute, the vendor, not the physician, bills Medicare for the drug (the physician continues to bill Medicare for the drug administration fee). For drugs not included in the CAP, physicians must continue to "buy and bill" using the normal Part B fee for service procedures for payment under the applicable methodology, usually ASP. One of the potential benefits of the CAP to participating physicians is that they will not need to collect drug cost sharing amounts owed by beneficiaries, thus reducing their risk of bad debt. The importance of this component to physicians will be addressed in the physician survey that will assess physician satisfaction with the program.

Medicare physicians are given an opportunity to elect to participate in the program on an annual basis each fall (although additional election periods have also been provided for in certain exigent circumstances). In the case of group practices, the election decision must be made at the group level. Physicians who decide to participate in the CAP are generally able to opt out of the program on an annual basis. However, CMS, in the July 6, 2005 regulations implementing the CAP, identified four reasons why physicians may opt out of the program early: (1) the vendor ceases to participate in the program; (2) the physician leaves a practice participating in the CAP; (3) if the physician moves to another competitive acquisition area, a criterion only relevant were there multiple competitive acquisition areas; (4) "other exigent circumstances defined by CMS," including if the vendor refuses to ship or otherwise provide an ordered drug. In subsequent regulations, CMS also allowed participating physicians to submit a written request to withdraw from the program within the first 60 days of the effective election date if the CAP proves to be an undue burden to the practice and after the first 60 days if an unexpected circumstance (e.g., change in practice personnel) arises.

6 A discussion of the targeting of drugs used by these specific specialties can be found at 70FR39029–31.

Under a "Furnish as Written" exception described in the NPRM, if the physician needs a specific formulation of a drug product in a HCPCS code on the CAP drug list within the physician selected category but that specific formulation is not supplied by the physician's chosen vendor, the physician obtains the drug privately and bills Medicare using the ASP methodology. In other words, the "Furnish as Written" provision provides the flexibility for a physician to obtain a specific formulation of a drug within a HCPCS code that is furnished under the CAP without requiring the vendor to stock every available drug product at the NDC level within a given HCPCS code.

Also, in emergency situations defined in the statute and regulation text the physician is allowed to administer a CAP drug to a Medicare beneficiary from the physician's own inventory and replace the drug by ordering from the vendor. An emergency situation may arise, for example, with cancer chemotherapy drugs; for these drugs, deviations from expected dates of drug administration are not unusual. For antibiotics and other anti-infectives, a patient's need for such a drug is generally unanticipated, and an order for the proper drug, dosage and amount may not be able to be placed and processed one or so weeks in advance. To use this provision, the physician must be able to demonstrate the drug administration met certain "emergency" criteria. The vendor then bills Medicare per the normal procedure.

Under the MMA statute for the CAP, the Secretary was permitted to limit the number of approved vendors in an area to no less than two. CMS implemented a single national competitive acquisition area. In addition, CMS decided against phasing-in the program by geographic areas or specialty.

CMS determined that they would select a maximum of the five lowest bidders from among the vendors who met quality and business criteria. Potential vendors were required to submit a bid to supply at least one NDC for each of the CAP HCPCS codes. The overall bid amount ranking among potential vendors was based on a composite average bid constructed from the individual HCPCS code bids and from volume weights. More specifically, CMS constructed a ''composite bid,'' from the bid amounts for the individual CAP HCPCS codes by weighting each HCPCS-specific bid amount by the HCPCS code's share of volume (measured in HCPCS units) of drugs in physician offices during the prior year (2004, the most recent complete year of Medicare claims data available at the time). The sum of these weighted amounts equaled the bidder's composite bid. According to the bidding process that CMS set up, these bidder-specific composite bids were required to be at or below the composite 106 percent of ASP payment amount (computed in the same way—e.g., using the bidding weights—as the bidders' composite bids). In this way, the resulting composite bid projected expected costs to the program of acquiring drugs from that vendor, assuming the 2004 volume in each HCPCS code turned out to be roughly proportional to CAP prescribed volume in later years. This reliance of the composite bids on projections of CAP prescribed drug volumes becomes important in understanding comparisons of CAP and ASP-based payment. Drugs subsequently added to the CAP after the bidding process received a payment amount equal to 106 percent of the ASP in effect when the drug (HCPCS code) was added to the CAP.

At the time the November 2005 NPRM was issued, some observers believed that the types of suppliers most likely to bid as vendors were specialty pharmacies and large national drug distributors, particularly those with specialty subsidiaries. Specialty pharmacies typically

deal in infused or injected drugs administered by a clinician. Some specialty pharmacies are subsidiaries of retail pharmacy chains, pharmacy benefit managers, or home health companies. This segment of the market is said to be dynamic, with new companies entering continuously (Health Strategies Consultancy, LLC, 2005). However, CMS also proposed requiring a minimum of at least three years' experience in the business of supplying injectables. According to the NPRM, 15 vendors submitted expressions of interest to CMS following publication of a Request for Information in December 2004. Most of the would-be vendors indicated a willingness to participate on a national basis. Several bidders submitted applications to become approved CAP vendors. Contracts were offered to the several bidders that met CAP criteria and submitted bids in the competitive range. Ultimately one bidder signed a contract with CMS to be an approved CAP vendor.

Finally, CMS determined that a specialized Medicare carrier would process CAP vendor claims and have other responsibilities. These include: medical review, oversight of CAP physician election agreements and physician requirements, compilation of vendors' program performance, data collection from the local physician carrier and the approved vendor, and educational and outreach about the CAP program to vendors and health care providers. As initially implemented, before a vendor claim could be paid in full by the Designated Carrier, drug administration had to be verified by matching the drug's CAP prescription order number on the physician's drug administration claim to the prescription order number on the vendor's CAP drug claim. The CAP prescription order number is generated by the vendor when the physician orders the drug, and the number is relayed to the physician. As originally implemented, Medicare's claims processing system uses the CAP order number to match the two claims and authorize payment for the vendor's drug claim. Noridian Administrative Services is the CAP Designated Carrier.

CAP implementation was originally scheduled for January 1, 2006. However, the ability of physicians to acquire drugs through the CAP was delayed until July 1, 2006 to give CMS additional time to refine the implementing regulations and to ensure that the CAP vendor, designated carrier, and electing practices were sufficiently prepared. Subsequently, CMS announced on September 10, 2008 that it would postpone further implementation the CAP as of December 31, 2008; as of the end of calendar year 2008 availability of drugs through an approved CAP vendor will be suspended until the CAP is reinstated.

Methodology and Data for the CAP Evaluation

This analysis uses a data set of CAP claims for drugs administered between July 1, 2006 and December 31, 2006. Any effects of seasonality were not considered in this analysis since it was based on six months of data and not an entire year. Some claims included in this analysis were initially denied claims for the period in which the sample was drawn. However, many of these claims were paid in April 2007 when the provisions of Section 108 of the Medicare Improvements and Extension Act of 2006 (MIEA-TRHCA, or Division B of the Tax Relief and Health Care Act of 2006) were implemented, and these claims were resubmitted. The MIEA-TRHCA required CMS to pay unpaid claims from the period July 1, 2006 to March 31, 2007 upon receipt of the claim, and to verify drug administration for claims paid under the MIEA-TRHCA with a post-payment review process. While this report was being written, post payment review on all claims in the sample had not been completed. As a result, certain specific aspects

of this report that are affected by the percentage of denied claims, including this report's comparison's of total payment for drugs under the CAP and associated comparisons to payment under ASP methodology, current potential program savings, and impact on beneficiary cost sharing amounts may be subject to change.

Analysis of beneficiary experiences was based on a series of qualitative in-person interviews conducted in four sites with a small sample (40) of beneficiaries whose physicians elected to participate in the CAP. The goal of these interviews was to determine if beneficiaries experienced any inconvenience, difficulty in access to medications, or satisfaction issues related to their physician's participation in the CAP.

Physicians' satisfaction with the CAP is being measured through a survey of 1,200 physicians whose practices elected the CAP and 1,200 physicians whose practices did not elect the CAP. Findings from this survey, which was fielded in the first half of 2008, could not be incorporated in this Report to Congress in order to meet the statutory deadline. The report on the survey will be completed in early spring, 2009 and will be available at that time. Only one report is required by statute; so, an additional report will not be formally submitted to Congress. In lieu of the results of this survey, this report analyses trends in physician participation and usage of CAP drugs as proxy measures.

Findings from the CAP Evaluation

Based on the evaluation completed to date, findings related to the mandated evaluation questions can be summarized as follows:

Range of Vendor Contracts

One of the mandated subjects of this evaluation report is the range of CAP vendors available to CAP-participating practices. Although multiple vendors participated in the bidding process, and contracts were offered to all bidders who met program requirements and were in the competitive range, only BioScrip signed a contract to become an approved CAP vendor. While not part of the original program design, participation of a single vendor in the competitive acquisition program may not represent an unsatisfactory choice for CAP-participating practices. The business model conforming most to the legislated program design, specialty pharmacy, is a highly concentrated industry with relatively few firms capable of fulfilling the requirements of the CAP. Since there were multiple CAP vendor bidders, the payment amount reducing effects of competition at the bidding stage may in part still be realized. Also, anticipating a gradual building of physician election in this program, having a single vendor may have allowed the vendor to be able to recoup the costs of developing the required billing and customer support systems better than if the early volume were divided among multiple vendors. Furthermore, the approved CAP vendor for the initial implementation period appears to have been capable of servicing the additional volume while providing the full range of CAP drugs.

Because only one bidder signed a contract to provide drugs under the CAP, the risk to the CAP program was increased because of potentially poor vendor performance. Were the vendor to have performance problems, physicians and beneficiaries might have associated the problems with CMS rather than the vendor. In addition, the participation of a single vendor eliminated choice within the CAP program. If physicians were unhappy with the vendor, they could not

switch vendors. Although there is continued interest in the CAP among physicians, it is impossible to know whether there would have been more interest had there been greater choice of vendors.

Comparison of Payment Amounts

The key source of potential cost savings associated with the CAP is the difference between CAP payment amounts and the payment amounts for the same drugs provided incident to physicians' services under the ASP (or "buy and bill") methodology. ASP payment amounts are set at 106 percent of the average sales price reported by manufacturers to CMS. During the first round of CAP bidding, bidders were required to base their bids on limits calculated from the October 2005 ASP price file. For weighted drugs, bidders could not exceed 106 percent of composite weighted ASP for the drugs in the single CAP category. In other words, these payment amounts were restricted so that the "composite bid," the sum of bid amounts weighted by the bidding weights, did not exceed 106 percent of the October 2005 average sales prices. The bidding weights were computed as the proportions of HCPCS units for each CAP drug among total HCPCS units for these drugs (administered by a physician in an office setting) in 2004. For unweighted drugs, bids on each drug could not exceed 106 percent of that individual drug's ASP. CMS based the payment amounts that CAP vendors receive for each drug on the median of the bids submitted by each bidder offered a CAP vendor contract. For drugs added to the CAP list as vendor-requested additions after the vendor bidding period, CAP payment amounts were set to 106 percent of the ASP in the quarter in which they were added.

The actual average payment amount under the CAP may differ from the calculated median of the composite bids for multiple reasons. First, actual utilization patterns of weighted CAP drugs among CAP-participating physicians differs from those of all Part B drug-administering physicians. When calculating bidding weights (prior to any knowledge of which physicians would participate), CMS used claims data for all physicians administering these drugs. If the physicians who ultimately participated are systematically different, with respect to utilization patterns of these drugs, then the actual average payment amount will differ from the median of composite bids. For example, CAP payments for immunomodulators, particularly infliximab (used predominantly by rheumatologists), accounted for 41 percent of the total payments for the 169 "weighted" drugs, compared to eight percent using assumptions based on pre-CAP (2004) data. Also, as discussed in the 2005 interim final and final rules, in response to public comments CMS adjusted CAP payment amounts based on the Producer Price Index (PPI) for prescription drugs in order to account for the time period that elapsed between the bidding period and the period in which the payment amounts were to be in effect. Since the composition of the CAP "basket" of drugs differs from that used for the PPI, it is possible that the ASPs for CAP drugs lagged inflation in drug prices overall. This may occur if CAP drugs happen to have a higher frequency of expiring patents than do prescription drugs in general (whether CAP drugs had a higher frequency of patent expiration than did other Part B drugs is not explored in this report).

To assess the differences between CAP payment amounts and fees based on 106 percent of the ASP, the analysis compared CAP payment amounts to ASP-based fees. In particular, whether CAP payment amounts were associated with higher (or lower) total allowed charges for the drug was determined. Findings suggest that, at least in the first six months of the program,

CAP payment amounts for drugs administered by participating physicians with dates of service between July 1 and December 31, 2006 were higher than under the ASP based alternative. Based on Medicare claims processed through April, 2007, on average (during 2006), the cost of drugs administered through the CAP exceeded 106 percent of ASP by approximately 3.5 percent. Since the majority of CAP drug payment amounts were set assuming the mix of Part B drugs administered through the CAP would be the same as the mix of all Part B drugs administered in 2004 and that ASPs would rise at the same rate as the PPI for prescription drugs,[7] CAP payment amounts should not, if these assumptions turned out to have been correct, have exceeded 106 percent of ASP. Also, this finding reflects the presence of claims that have not been finalized. CMS announced that CAP payment amounts for 2008 would average about 2.3 percent less than 2007 payment amounts to account for changes in the net acquisition costs of CAP drugs and ASP-linked payment amount limits. In addition, bidding weights for future rounds of vendor bidding will reflect the mix of drugs ordered by CAP-participating physicians, which was not possible when setting bidding weights for the initial implementation of the program. This may have important impacts on future assessments of differences between CAP payment amounts and 106 percent of ASP fees.

Program Savings

The Congress also required the Secretary to evaluate the overall Medicare program savings as a result of the CAP. To address this question, this report analyzed the difference between 106 percent of ASPs and CAP payment amounts (actual or estimated through the end of 2008, when the current CAP contract ends) as a measure of the actual and expected savings under the CAP, rather than also including changes in utilization. A number of reasons underlay this approach. First, physicians began acquiring drugs under the CAP only in the second half of 2006, so only six to twelve months' data would be available to analyze for this report. In addition, the Congressionally-mandated requirement to pay the CAP vendor's claims upon receipt and verify drug administration on a post-payment basis implemented on April 1, 2007 will result in some claims being processed, paid, and then retroactively denied. Making inferences about program and beneficiary savings from this early participation period may provide unreliable estimates of the true program and beneficiary savings. There was insufficient data for comparisons of cost and utilization between CAP-electing and non-electing physicians to be statistically valid due to the small number of participating physicians. Consequently, CMS was unable to directly compare CAP-electing and non-electing physicians during 2006.

CAP payment amounts and ASPs in place during this period, however, are known. Therefore, to measure the actual observed impact of differences between CAP payment amounts and 106 percent of ASPs, and to estimate the impact of future payment amounts, a CAP drug "price" index was developed.

In summary, this analysis on six months' data projects that for the first 18 months of physician participation in the CAP, CAP payment amounts, on average, will exceed 106 percent

7 As discussed in Chapter 4 of this report, the average actual ASP for the weighted CAP drugs fell by nearly one percent, whereas the PPI for prescription drugs rose nearly five percent between 2005 and 2006.

of the ASPs for CAP drugs.[8] This was the result of a critical decision made in 2005, prior to knowledge of subsequent changes in ASPs, to update CAP payment amounts for the CAP drugs with payment amounts based on competitive bidding using the PPI for prescription drugs. Had these payment amounts not been updated, the CAP would have reduced Medicare program and beneficiary expenditures on these drugs. However, over the full 30-month period of the first CAP vendor contract, it is expected that the CAP will be approximately budget neutral. This expectation is based on trend analysis of recent ASPs for these drugs[9] and recent downward adjustment to CAP payment amounts for the vendor's lower acquisition costs. Beneficiaries receiving CAP drugs from a CAP-participating practice for this entire period would likely not be materially financially affected, positively or negatively, by the CAP. Beneficiaries receiving drugs through the CAP in 2006 and 2007 had co-insurance payments for these drugs between 0.4 percent (during late 2007) and 3.7 percent (during mid-late 2006) higher than would have been the case had their physician's practice not elected to participate in the CAP. The highest likelihood of CAP payment amounts exceeding ASP payment amounts occurred early in the program. In contrast, beneficiaries who receive CAP drugs from CAP-participating practices in 2008 will likely experience coinsurance payments three to five percent lower than beneficiaries who do not receive CAP drugs from a CAP-participating practice. This is due in part to estimated increases in ASPs (assuming pre-existing price trends continue into 2008) and in part to the 2.3 percent average CAP payment amount reduction in the annual adjustment for 2008.

Reductions in Cost Sharing

There was no apparent evidence of systematic change in cost sharing for beneficiaries as a result of the CAP, either from reductions in Part B drug payment rates or through evidence reported by beneficiaries. Analysis of potential beneficiary cost sharing as a result of payment changes in CAP relative to 106 percent of ASP suggested that there were very limited to no savings that resulted from the CAP program relative to the standard 106 percent of ASP payment in 2006. One potential source of beneficiary cost sharing impact could result from some systematic change in likelihood that beneficiaries will actually be charged their co-insurance. However, neither early CAP development work nor interviews with beneficiaries for this analysis suggested that forgiveness of co-insurance was a common practice among physicians either before, or after, CAP implementation.

Patient Satisfaction

Patient interviews indicated that most beneficiaries seem to be unaffected by their physicians' participation in the CAP and in fact have little or no sense of any changes having occurred that might be attributable to their physicians' participation in the CAP. While a few beneficiaries reported an increase in return appointments necessary to receive drug regimens

8 Claims data were only available for 2006; program savings estimates assume that average quarterly CAP volume in 2007 equals that for the third and fourth quarters of 2006. Since CAP participation rose in 2007, a period when program savings deficits were smaller than in 2006, it may be that actual program savings deficits in 2007 are smaller than reported in this chapter, or even in fact savings surpluses.

9 Forecasting future ASPs by projecting forward linear trends of prior ASPs may yield significant error in some cases, especially for drugs with expiring patents. However, since predicting future prices for those drugs is very difficult, this report uses linear time trends for simplicity and ease of understanding potential biases.

under the CAP, it was unclear whether these additional visits were related to drug availability or clinical decision. One beneficiary reported better, availability of the Part B drug he uses under the CAP compared with the period before the CAP was implemented. Therefore, from this analysis, there seems to be no detectable systematic negative impact of the CAP on Part B beneficiary satisfaction.

Access to Competitively Bid Drugs

Two separate analyses assessed whether beneficiaries may have encountered Part B drug access problems as a result of their physician(s) participating in the CAP. One method gathered feedback from one-on-one interviews with beneficiaries whose physicians elected to participate in CAP. During the interviews, beneficiaries were specifically asked whether they encountered problems such as rescheduling of visits, or inability to receive the drug altogether, as a result of the drug not being delivered to the physician's office or because of the approved CAP vendor refusing to supply the drug. While some beneficiaries reported instances of return visits to received drug regimens, these cases were not described as inconveniences, and may simply have been clinical decisions that would have occurred regardless of CAP. The beneficiaries interviewed reported no systematic perceptions of problems getting access to Part B drugs.

A second method, using Medicare claims data, examined the rate at which physicians in CAP-participating practices (CAP physicians) have relied on the Furnish as Written (FAW) and Emergency Restocking provisions of the CAP. Because early claims data were included in this analysis, some of the claims for the drugs administered using the Emergency Restocking provisions of the CAP may not ultimately be determined to be payable by the Medicare program once the post payment review process is complete.

The FAW provision was intended to enable a CAP physician to provide a specific dosage, concentration, or formulation of a CAP drug to a patient when the specific NDC (drug, formulation, concentration, package size, and manufacturer) is not available through the approved CAP vendor. Approved CAP vendors must agree to supply at least one NDC within each of the HCPCS codes included in the CAP. Under the FAW provision, when a particular formulation of a CAP drug is not available from the vendor the CAP physician obtains the drug privately and bills Medicare for it under the ASP program just as he or she would for any drug not on the CAP drug list. A high rate of use of the FAW provision may mean that some of the NDCs the vendor has chosen to supply within the CAP may not be the particular formulation of a drug that a CAP physician needs or wants to supply to his or her patients. While there seemed to be relatively high rates of use by physicians of the FAW in the first six months of the program (11 percent)—at least compared to CMS's presumed intention of their use as uncommon—there is no indication that this demonstrated a problem with beneficiary access to drugs. On the contrary; physicians are invoking an element of the CAP *specifically designed* to prevent access issues. The use of the emergency restocking and Furnish as Written provisions did, ultimately, result in beneficiaries receiving their prescribed drugs.

The Emergency Restocking provision helps to ensure beneficiaries receive timely access to drugs in urgent situations by allowing the physician to submit an order retrospectively to resupply a drug provided from the physician's own inventory. As legislated in the MMA and implemented by CMS, physicians are advised to use the Emergency Restocking provision if:

(1) the drug is required immediately; (2) the need for the drug could not be anticipated; (3) the CAP vendor would not be able to ship the drug to the physician in a timely manner if an order were placed; and (4) the drug was administered in an emergency situation provisions. The high use of the Emergency Restocking provision found in this evaluation (approximately 46 percent of CAP claims in the first six months of the program) could be a sign of potential access problems, or it could reflect physicians adapting to when best to use this provision under the newly implemented program. This provision, used most often for infections based on initial data, could require CAP-participating practices to maintain a stock of drugs at some financial risk. The practices can minimize this financial risk by decreasing their drug inventory as a result of participating in the CAP, but completely avoiding this risk in practices that administer drugs in urgent and changing clinical circumstances is not possible because CAP drugs cannot be stocked at a physician's office. However, physicians who provide these drugs generally maintain an inventory of drugs for their non-Medicare patients and for use for new patients who may need the drug administered in an emergency situation. As a result, providing these drugs to their Medicare patients in situations which they deemed to be an emergency may not have been a hardship. It may be the case that physicians utilizing the Emergency Restocking provision for multi-week regimens of intravenous antibiotics misunderstood the intention of emergency restocking or it could mean that a needed order of a drug did not arrive timely for whatever reason. After the physician determines the patient needs to have the drug administered daily for multiple weeks, the patient's need for the drug may be well anticipated.

Satisfaction of Physicians

Although further implementation of the CAP program has been postponed as of December 31, 2008, long-term viability of the CAP when reinstated may be influenced by physicians' satisfaction with the program. If physicians are dissatisfied with the program, they may not elect to continue to participate in the program, and future rounds of bidding for CAP vendors may fail to attract bidders. Physicians' satisfaction with the CAP is being measured through a survey of 1,200 physicians whose practices elected the CAP in 2006 or 2007 and 1,200 physicians whose practices did not elect the CAP. This survey, which was fielded in the first half of 2008 (and therefore not available for analysis in time for the results to be included in this mandated report) included questions on why practices did, or did not, elect the CAP; physicians' satisfaction with acquiring drugs under the CAP and under the standard "buy-and-bill" method; and physician demographics and typical drugs administered.

In lieu of the results of the physician survey, an alternative method of understanding whether physicians are satisfied with the CAP is analyzing practices' decisions to elect, or not elect, the CAP for 2007, particularly practices that elected the CAP in 2006. A significant proportion (45 percent) of the practices participating in the CAP in the first six months of the program opted not to participate in 2007. Although this rate of deciding not to re-elect the CAP may seem large, it is important to note that 2006 was only the first six months of physician participation in this program. A number of practices may have elected in 2006 as a "trial" period since they were required to participate for only six months and they may have had a low rate of Part B drug administration. The number of practices electing the CAP in 2007 has risen to 938 (representing a total of 3,247 physicians, several times the number of physicians who participated initially). Although nearly 200 practices (566 physicians and practitioners) opted not to re-elect for 2007, more than 700 practices (nearly 2,300 physicians and practitioners) elected

for the first time in 2007. This presumably indicates continued interest with the program for these practices.

CHAPTER 1
INTRODUCTION

1.1 Background

Prescription drugs covered by Medicare Part B generally include drugs administered "incident to" a professional service, drugs administered through durable medical equipment (DME), and certain drugs covered by statute. Medicare Part B covers a variety of drugs, such as: anticancer (chemotherapy) drugs; drugs for diseases such as rheumatoid arthritis and Crohn's disease; nebulized drugs for patients with COPD and asthma; some vaccines; clotting factors; blood products; and IV immunoglobulins for immunocompromised patients. For the subset of drugs that are covered under the "incident to" provision, the cost of the drug must represent a real cost to the physician; a physician generally cannot bill Medicare and the beneficiary for drugs purchased by another entity (e.g., a hospital, a pharmacy, etc). In other words, a physician had to be financially liable for the cost of the drug. Thus the MMA introduced a new type of supplier, CAP vendors, financially liable for the cost of Part B drugs despite not administering drugs to patients.

Medicare Part B drugs can be administered on an outpatient basis in a variety of settings and locations, such as professional offices, hospital outpatient departments (HOPDs), freestanding clinics, and beneficiaries' homes. Medicare's payment for these drugs varies depending on the provider administering the drug and the drug being administered. For example, HOPDs (under the Hospital Outpatient Prospective Payment System) are paid separately for only a selected set of Part B-covered drugs. In contrast, physicians, suppliers, and DME suppliers receive separate payment for the vast majority of Part B drugs they administer (in addition to being paid the professional fee for administering the drug), subject to Local and National Coverage Determinations (LCDs and NCDs).[10] Thus the amount paid by Medicare (and by the beneficiary as co-insurance) for these drugs depends critically on where the drug is administered.

Beginning in 1992, payment limits for Part B drugs were based on the lower of 100 percent of the average wholesale price (AWP) or the estimated acquisition cost (EAC). This policy was implemented through the use of the list AWP, a commercially-published list price that may not reflect actual prices paid to wholesalers after various kinds of discounts. Under the Balanced Budget Act of 1997 (BBA; Pub. L. 105-33) drugs not paid on a cost or prospective payment basis were paid based on the lower of the actual charge or 95 percent of AWP. Through rulemaking, CMS based payments for drugs with generic versions available on 95 percent of the lower of the median AWP for all generic forms or the lowest brand-name AWP. For payments in 2004, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; Pub. L. 108-173) revised the payment limits for drugs not paid on a cost or prospective payment basis to the lower of 85 percent of AWP, with certain drugs having statutory exceptions to this revised payment methodology.

10 Medicare Carriers and Program Safeguard Contractors are required to apply all LCDs and NCDs to all claims for drugs acquired through the CAP and to all drug administration services.

In part to compensate for the reduction in payment rates for Part B drugs mandated by the MMA beginning in 2004, and to respond to criticism that higher payment rates for drugs were necessary to offset inadequate payments for administration, drug administration service fees under the Medicare Physician Fee Schedule (MFS) were increased between nine and 459 percent, depending on the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code used for billing for drug administration, including a 32 percent one-year transition adjustment.[11] Specifically, Section 303(a) of the MMA required CMS to provide Work Relative Value Units (RVUs) for drug administration services and also to provide a "transition adjustment" in payment for these services of 32 percent in 2004 and three percent in 2005. ***Exhibit 1-1*** presents the impact between 2003 and 2004 on payments for selected drug administration services.

Exhibit 1-1. Impact of MMA-mandated Medicare physician fee schedule changes on Medicare payment for selected drug administration services

CPT code	Description	2003 Payment	2004 Payment without transition	Percentage change without transition (%)	2004 Payment with transition	Percentage change without transition (%)
90780	IV infusion therapy, 1 hour	$ 42.67	$ 89.23	109.1 %	$ 117.79	176.1 %
90781	IV infusion, additional hour	21.70	25.02	15.3	33.02	52.2
90782	Injection, subcutaneous/intramuscular	4.41	18.67	323.4	24.64	458.7
96400	Chemotherapy, subcutaneous/intramuscular	37.52	48.54	29.4	64.07	70.8
96408	Chemotherapy, push technique	37.52	117.24	212.5	154.76	312.5
96410	Chemotherapy, infusion method	59.22	164.66	178.1	217.35	267.0
96412	Chemotherapy, infusion method add-on	44.14	36.59	−17.1	48.30	9.4

SOURCE: Table 10 in the Medicare Physician Fee Schedule Interim Final Rule for Calendar Year 2004 (69FR1108).

Although the MFS changes were designed to fully compensate for drug payment amount reductions, some physician groups, particularly oncologists/hematologists, have denied that parity was achieved. According to press reports, some have reduced the scope of their oncology services or referred patients to hospitals for chemotherapy treatments.

The Part B payment system continued to evolve under further MMA mandates. As required by the MMA, Congress introduced market-based reform for drugs not paid on a cost or prospective basis. Two new payment methodologies were created. Section 303(c) of the MMA, amending Title XVIII of the Social Security Act by adding Section 1847A, required that payment for the vast majority of physician-administered Part B drugs be based on the Average Sales Price (ASP) for each drug, beginning in January 2005. The average sales prices, reported quarterly by drug manufacturers, are the average prices paid for each Part B drug by all purchasers, net of any discounts.[12] The ASP is based on the manufacturer's average price per

11 See Table 10 in the Medicare Physician Fee Schedule Interim Final Rule for Calendar Year 2004 (69FR1108), reprinted in Section 1 of this report, for details.

12 Subsequent CMS regulations have clarified that purchases of Part B drugs by vendors selected to provide drugs under the Competitive Acquisition Program for Part B Drugs are excluded from ASP computations.

unit as represented by the 11-digit National Drug Code (NDC) for all sales excluding certain sales exempted by statute. Exceptions to the ASP-based pricing methodology are possible under MMA if, for example, the Office of the Inspector General finds that the ASP exceeds the widely available market price or average manufacturer price by a specified threshold and informs the Secretary at such times as the Secretary may specify.

Although the conversion to ASP based pricing was a significant change in Medicare *payment* for these drugs, it did not significantly change the *method* by which physicians acquire drugs. Physicians receiving payment under Section 1847A of the Social Security Act still "buy and bill" for Part B drugs they administer.

1.2 Congressional Mandate for a Competitive Acquisition Program

Another MMA mandated Part B-covered drug payment reform—and the focus of this evaluation—is the introduction of physician acquisition of certain Part B drugs through the CAP in July 2006.[13] Section 303(d)(2) of the MMA, which added Section 1847B of the Social Security Act, required the implementation of a competitive acquisition program for Part B drugs (the CAP). Under this program, CAP-participating physicians would submit an order for a drug prior to the patient's visit from a vendor selected by CMS through a competitive acquisition process. After the physician administered the drug, the physician would submit a claim for the drug administration procedure, but not for the drug itself. However, the physician would indicate the drug on the claim, along with the order number. The vendor providing the drug would bill the beneficiary and the Medicare program for the drug.

To begin the process of CAP implementation, the Centers for Medicare & Medicaid Services (CMS) issued a Notice of Proposed Rulemaking (NPRM) for the CAP program on March 4, 2005. This NPRM laid out a number of fundamental design decisions for the CAP program for which CMS solicited public comment. Subsequently, further interim final and final rules were released as necessary in response to public comments, legislative changes, and other circumstances.

As outlined in the March 2005 NPRM, CMS proposed that drugs eligible for inclusion in the CAP consist of drugs administered incident to a physician's service and described in Section 1842(o)(1)(C) of the Social Security Act. CMS also specifically proposed to exclude blood products, vaccines, drugs infused through DME, and drugs usually dispensed by pharmacies (e.g., oral immunosuppressive drugs). Further, under the MMA statute, the Secretary has the authority to exclude from the programmatic group any drugs and biologicals whose inclusion is unlikely to result in cost savings or whose inclusion would have an adverse effect on access. Regarding the drugs included in the initial round of CAP bidding, CMS initially selected a set of 169 Part B drug HCPCS codes (out of more than 500), representing approximately 85 percent of allowed charges for physicians' Part B drugs that satisfied a set of criteria. Medicare Part B-covered vaccines, drugs infused through a covered item of durable medical equipment, and blood

13 CAP implementation was originally scheduled for January 1, 2006. However, the ability of physicians to acquire drugs through the CAP was delayed until July 1, 2006 to give CMS additional time to refine the implementing regulations and to ensure that the CAP vendor, Designated Carrier, and electing practices were sufficiently prepared.

and blood products were excluded due to statutory restriction. Further, several other classes of drugs were excluded using statutory authority: erythropoietin administered to ESRD patients; intravenous immune globulins; oral anti-emetic and anti-cancer drugs; controlled (Schedules II, III, IV, and V) substances; clotting factors; tissue; low volume drugs (with less than $1 million in allowed charges in office settings in 2004 or $250,000 for anti-infectives, antidotes, and cardiovascular agents); and unclassified/not otherwise classified (NOC) drugs.[14] Certain other specific drugs, including specific forms of leuprolide, were also excluded.

The final set of drug HCPCS codes for initial bidding was drawn from the set of drugs remaining after the above exclusions were applied. First, drugs determined to be most often administered by oncology specialties (hematology, hematology/oncology, medical oncology, surgical oncology, urology, and gynecology/oncology)—oncolytics, chemotherapy adjuncts, anti-emetics, and hematologics—were included in an interim list. In addition, drugs used relatively often (appearing on at least one percent of Part B drug-containing claims) by ophthalmologists, psychiatrists (including addiction medicine and neuropsychiatry), and rheumatologists, were also included.[15] A total of 169 HCPCS codes were identified using this procedure, and bidding weights were computed based on relative volume. These drug HCPCS codes are the "weighted drugs." At the time, under the assumption that CAP payment amounts for these drugs would equal 106 percent of ASP, about 38 percent of CAP payments would be for cancer chemotherapy; 35 percent for hematologics, mostly for the hematopoietic drugs epoetin alfa and darbepoetin alfa; and eight percent for immunomodulators, mostly for infliximab (used for rheumatoid arthritis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

In addition to the weighted drug list, CMS added a set of drugs with HCPCS codes assigned in 2005; these drug HCPCS had no Medicare volume in 2004 (used in the CAP drug selection criteria described above). After adding these new drugs, and making other adjustments for changes in HCPCS coding, for 2006, a total of 182 Part B drugs were included in the CAP to be provided by the CAP vendor.

Physician participation in the CAP is voluntary. Physicians who elect to participate in the CAP must generally, with some allowable exceptions, acquire drugs covered by the CAP from a vendor selected by the CMS through the competitive bidding program. Under this method, participating physicians submit an order to the vendor, and the vendor then ships the drug to the physician. By statute, the vendor, not the physician, bills Medicare for the drug (the physician continues to bill Medicare for the drug administration fee). For drugs not included in the CAP, physicians must continue to "buy and bill" using the normal Part B fee for service procedures for payment under the applicable methodology, usually ASP. One of the potential benefits of the CAP to participating physicians is that they will not need to collect drug cost sharing amounts owed by beneficiaries, thus reducing their risk of bad debt. The importance of this component to physicians will be addressed in the physician survey that will assess physician satisfaction with the program.

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14 NOC drugs could be added later to the CAP on a case-by-case basis. They were excluded from bidding because of the lack of claims data necessary for computing bidding weights.

15 A discussion of the targeting of drugs used by these specific specialties can be found at 70FR39029–31.

Medicare physicians are given an opportunity to elect to participate in the program on an annual basis each fall (although additional election periods have also been provided for in certain circumstances). In the case of group practices, the election decision must be made at the group level. Physicians who decide to participate in the CAP are generally able to opt out of the program on an annual basis. However, CMS, in the July 6, 2005 regulations implementing the CAP, identified four reasons why physicians may opt out of the program early: (1) the vendor ceases to participate in the program; (2) the physician leaves a practice participating in the CAP; (3) if the physician moves to another competitive acquisition area, a criterion only relevant were there multiple competitive acquisition areas; (4) "other exigent circumstances defined by CMS," including if the vendor refuses to ship or otherwise provide an ordered drug. In subsequent regulations, CMS also allowed participating physicians to submit a written request to withdraw from the program within the first 60 days of the effective election date if the CAP proves to be an undue burden to the practice and after the first 60 days if an unexpected circumstance (e.g., change in practice personnel) arises.

Drugs supplied under the CAP are billed to Medicare by the approved CAP vendor through a specialized Medicare carrier (called the Designated Carrier), and the vendor in turn bills the beneficiary (and supplementary insurer) for any applicable co-insurance or deductible. Under a "Furnish as Written" exception described in the NPRM, if the physician needs a specific formulation of a drug product in a HCPCS code on the CAP drug list within the physician selected category but that specific formulation is not supplied by the physician's chosen vendor, the physician obtains the drug privately and bills Medicare using the ASP methodology. In other words, the "Furnish as Written" provision provides the flexibility for a physician to obtain a specific formulation of a drug within a HCPCS code that is furnished under the CAP without requiring the vendor to stock every available drug product at the NDC level within a given HCPCS code.

Also, in emergency situations defined in the statute and regulation text the physician is allowed to administer a CAP drug to a Medicare beneficiary from the physician's own inventory and replace the drug by ordering from the vendor. An emergency situation may arise, for example, with cancer chemotherapy drugs; for these drugs, deviations from expected dates of drug administration are not unusual. For antibiotics and other anti-infectives, a patient's need for such a drug is generally unanticipated, and an order for the proper drug, dosage and amount may not be able to be placed and processed one or so weeks in advance. To use this provision, the physician must be able to demonstrate the drug administration met certain "emergency" criteria. The vendor then bills Medicare per the normal procedure.

Under the MMA statute for the CAP, the Secretary was permitted to limit the number of approved vendors in an area to no less than two. CMS implemented a single national competitive acquisition area. In addition, CMS decided against phasing-in the program by geographic areas or specialty.

CMS determined that they would select a maximum of the five lowest bidders from among the vendors who met quality and business criteria. Potential vendors were required to submit a bid to supply at least one NDC for each of the CAP HCPCS codes. The overall bid ranking among potential vendors was based on a composite average bid constructed from the individual HCPCS code bids and from volume weights. More specifically, CMS constructed a

‘‘composite bid,’’ from the bid amounts for the individual CAP HCPCS codes by weighting each HCPCS-specific bid amount by the HCPCS code’s share of volume (measured in HCPCS units) of drugs in physician offices during the prior year (2004, the most recent, at the time, complete year of Medicare claims data). The sum of these weighted amounts equaled the bidder’s composite bid. According to the bidding process that CMS set up, these bidder-specific composite bids were required to be at or below the composite 106 percent of ASP payment amount (computed in the same way—e.g., using the bidding weights—as the bidders’ composite bids). In this way, the resulting composite bid projected expected costs to the program of acquiring drugs from that vendor, assuming the 2004 volume in each HCPCS code turned out to be roughly proportional to CAP prescribed volume in later years. This reliance of the composite bids on projections of CAP prescribed drug volumes becomes important in understanding comparisons of CAP and ASP-based payment. Drugs subsequently added to the CAP after the bidding process received a payment amount equal to 106 percent of the ASP in effect when the drug (HCPCS code) was added to the CAP.

Under the CAP methodology, the vendor’s bid amounts were required to cover all costs of acquisition, management, and delivery, but must exclude physician administration costs and wastage. However, to win approval, a bidder’s composite bid could not be equal to or higher than the weighted average payment amounts from the ASP system (using HCPCS unit volumes from 2004—the most recent available at the time—and the October 2005 ASPs). Under the law, CAP vendor contracts are awarded for three years.[16] A process for updating the payment amounts for drugs supplied under the CAP was required by the MMA. CAP vendors must report their net acquisition costs for the drugs covered under the contract, and CMS has proposed that this be provided annually. Cost information will be used annually to determine whether the following year’s CAP payment amounts should be adjusted upwards or downwards.

The approved CAP vendors’ licensure requirements were based on the statute and applicable State law. Because Part B drugs are prescription drugs, they can only be sold to patients by licensed pharmacies. However, sales to physicians can be made by licensed wholesalers (whose licensure requirements are much less stringent). The MMA mandated that physicians not be involved financially in the CAP transaction; vendors bill Medicare and beneficiaries directly. As a result, CAP transactions could not be structured as sales to physicians since physicians are not financially involved. Vendors, therefore, almost surely need a pharmacy license—however, CMS regulations only required that vendors comply with all applicable laws and regulations. Specific types of licensure were not specified.

At the time the November 2005 NPRM was issued, some observers believed that the types of suppliers most likely to bid as vendors were specialty pharmacies and large national drug distributors, particularly those with specialty subsidiaries.[17] Specialty pharmacies typically deal in

16 Physician acquisition of drugs from the CAP vendor began in July 2006, so the effective length of the first CAP bidding period was in fact 30 months over three calendar years: 2006 through 2008.

17 CMS made no specific requirements other than participating vendors had to comply with all State laws and regulations. The specific requirements are listed in 72 FR 66274 (the final rule for the MFS, which included a section on the CAP): “(a) Licensure Requirements for CAP Pharmacies and Distributors. As specified in [42 CFR] 414.914, approved CAP vendors and their subcontractors must meet applicable licensure requirements in each State in which it supplies drugs under the CAP. This includes appropriate licensure in States that the CAP

infused or injected drugs administered by a clinician. Some specialty pharmacies are subsidiaries of retail pharmacy chains, pharmacy benefit managers, or home health companies. This segment of the market is said to be dynamic, with new companies entering continuously (Health Strategies Consultancy, LLC, 2005). However, CMS also proposed requiring a minimum of at least three years' experience in the business of supplying injectables. According to the NPRM, 15 vendors submitted expressions of interest to CMS following publication of a Request for Information in December 2004. Most of the would-be vendors indicated a willingness to participate on a national basis. Several bidders submitted applications to become approved CAP vendors. Contracts were offered to those bidders who met CAP criteria and submitted bids in the competitive range. Ultimately one bidder signed a contract with CMS to be an approved CAP vendor.

Finally, CMS determined that a specialized Medicare carrier would process CAP vendor claims and have other responsibilities. These include: medical review, oversight of CAP physician election agreements and physician requirements, compilation of vendors' program performance, data collection from the local physician carrier and the approved vendor, and educational and outreach about the CAP program to vendors and health care providers. As initially implemented, before a vendor claim could be paid in full by the Designated Carrier, drug administration had to be verified by matching the drug's CAP prescription order number on the physician's drug administration claim to the prescription order number on the vendor's CAP drug claim. The CAP prescription order number is generated by the vendor when the physician orders the drug, and the number is relayed to the physician. As originally implemented, Medicare's claims processing system uses the CAP order number to match the two claims and authorize payment for the vendor's drug claim. Noridian Administrative Services is the CAP Designated Carrier.

CMS solicited bids for CAP vendors for the 2009 calendar year CAP program and received several qualified vendor bids. Subsequently, CMS announced on September 10, 2008 that it would postpone further implementation the CAP as of December 31, 2008. As of the end of calendar year 2008 availability of drugs through an approved CAP vendor will be suspended until the CAP is reinstated (CMS Competitive Acquisition Program Announcement, September 10, 2008).

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vendor ships drug to even though the vendor does not maintain a physical establishment in these States. In the July 6, 2005 IFC [interim final rule with comment period] (70 FR 39066), [CMS] stated that a vendor, its subcontractor, or both must be licensed appropriately by each State to conduct its operations under the CAP. Therefore, a vendor under the CAP would be required to be licensed as a pharmacy, as well as a distributor if a State requires it. It is the CAP vendor's responsibility to determine which State and national requirements it must adhere to." In the July 6, 2005 IFC (70 FR 39066) CMS also stated that "nothing in section 1847B of the [Social Security] Act shall be construed as waiving applicable State requirements relating to the licensing of pharmacies."

Exhibit 1-2 displays a timeline for CAP implementation.

Exhibit 1-2. Timeline of CAP implementation

Date	Implementation activity
April 20, 2004	Special Open Door Listening Forum to solicit input from interested parties on several design and implementation issues.
August 10, 2004	Contracted with RTI International to assist with the development of implementation alternatives. This includes consultations with several provider, beneficiary, and industry organizations.
December 13, 2004	Issued a Request for Information (RFI) to assess interest in bidding to be a CAP vendor. CMS received 15 responses. Many indicated an interest in serving a single, nationwide area. Four expressed interest in providing a wide range of drugs used by most specialties.
March 4, 2005	Issued a Proposed Rule (CMS–1325–P) describing its plan for implementing the CAP as well as several options for drugs included in the program (including phase-in of drugs), physicians able to elect to participate, and acquisition areas. Options were presented to obtain additional feedback from interested parties.
July 6, 2005	Issued Interim Final Rule with Comment Period (CMS–1325–IFC) responding to comments on the March 4, 2005 Proposed Rule. The rule clarified that the program will include a broader range of drugs, rather than only oncology drugs. Based on HCPCs designated in 2004, CMS identified a list of 169 drugs to be covered in the initial phase of the CAP, representing approximately 85% of physicians' Part B drugs by allowed charges.
August 3, 2005	CMS temporarily suspended vendor bidding in order for CMS to review public comments on the IFC and to clarify the bidding process. Originally, bids for CAP vendors were due on August 5, 2005.
November 21, 2005	Issued CMS-1325-F (published with CMS-1502-FC). The bidders' drug list was updated, processes for adding drugs to the CAP was announced, and interim responses to public comments from earlier rules were published. Also issued Interim Final Rule with Comment Period (CMS–1325–IFC3) to respond to comments regarding excluding CAP-provided drugs from ASP calculations. Bids from prospective vendors were accepted from November 21, 2005 to December 22, 2005.
December 1, 2005	Open Door Forum for prospective vendors.
March 31, 2006	Initial acceptance letters were sent to selected bidders, including the final CAP payment amounts, a CMS contract to be reviewed and signed by the accepting vendor, and an invitation to attend a CAP implementation workshop. The deadline for contract acceptance was April 10, 2006. The payment rates for the drugs are based on the median bid amount from several bidders' submissions.

(continued)

Exhibit 1-2. Timeline of CAP implementation (continued)

Date	Implementation activity
April 21, 2006	CMS announced that BioScrip, Inc. accepted the contract to be a CAP vendor. BioScrip stated that it would provide more than 180 drugs and biologicals under CAP, including several drugs that were not assigned HCPCS codes at the time that the initial list of biddable drugs was developed.
May 8, 2006	First round of physician election began, and it ended on June 2, 2006. The participation period for physicians electing at this time was July 1, 2006 through December 31, 2006.
June 3, 2006	CAP physician election extended from the period June 2 to June 30, 2006. The participation period for physicians electing at this time was August 1, 2006 through December 31, 2006.
August 24, 2006	CMS and Noridian Administrative Services, the Designated Carrier for the CAP, presented a teleconference on CAP billing and claims submission requirements.
October 1, 2006	Physician election for 2007 began, and it ended on November 15, 2006. The participation period for physicians electing at this time was January 1, 2007 through December 31, 2007.
April 1, 2007	CMS and its contractors began implementing the post-payment review process mandated by the Tax Relief and Healthcare Act of 2006 (MEIA-TRHCA).
May 1, 2007	An additional round of physician election began, and it ended on June 15, 2007. The participation period for physicians electing at this time was August 1, 2007 through December 31, 2006.
July 12, 2007	CMS promulgated Proposed Rules based on the MEIA-TRHCA legislation, mandating two changes to the CAP. First, Medicare program payments to CAP vendors are made upon receipt of the vendor's claim, not after acceptance of the physician's drug administration claim. Second, CMS established a post-payment review process to determine if payments to vendors should have been made.
October 1, 2007	Physician election for 2008 began, and it ended on November 15, 2007. The participation period for physicians electing at this time was January 1, 2008 through December 31, 2008.
November 27, 2007	CMS promulgated Final Rules based on the MEIA-TRHCA legislation, mandating two changes to the CAP. First, Medicare program payments to CAP vendors are made upon receipt of the vendor's claim, not after acceptance of the physician's drug administration claim. Second, CMS established a post-payment review process to determine if payments to vendors should have been made.

(continued)

Exhibit 1-2. Timeline of CAP implementation (continued)

Date	Implementation activity
December 7, 2007	Presolicitation Notice for potential CAP vendors released. The bidding period for CAP vendors for the period January 1, 2009 to December 31, 2011 is scheduled to begin on January 14, 2008 and end on February 15, 2008.
January 3, 2008	CMS announced an additional CAP physician election period for 2008. The period will begin on January 15, 2008 and end on February 15, 2008. The participation dates for physicians electing at this time will be April 1, 2008 through December 31, 2008.
September 10, 2008	CMS announced a postponement of the CAP program, effective December 31, 2008. As of the end of calendar year 2008 availability of drugs through an approved CAP vendor will be suspended until the CAP is reinstated.

SOURCE: Namovicz-Peat (2007); various Proposed and Final Rules published in the Federal Register.

1.3 CAP Evaluation Mandate and Organization of This Report

In addition to mandating the implementation of the CAP, the Congress also required the Secretary to submit an evaluation of this program. Specifically, the Secretary is required to report on:

1. The range of vendors available to CAP-participating physicians
2. Comparison of payment amounts under the CAP versus 106 percent of ASP
3. Program savings
4. Reductions in cost-sharing
5. Satisfaction of patients whose physicians have elected to participate
6. Access to competitively biddable drugs and biologicals
7. Satisfaction of physicians electing to participate.

This report is organized with a chapter for each of the Congressionally mandated evaluation issues. Chapter 2 considers the outcome of designation of a single vendor, BioScrip, with respect to the range of potential vendors with business models capable of performing within the Congressionally-mandated CAP structure. Chapter 3 compares CAP payment amounts to the 106 percent of ASP fees paid to physicians not participating in the CAP, and Chapter 4 evaluates the actual and expected program savings realized by the CAP. Chapter 5 considers whether there have been any changes in physician and beneficiary cost-sharing of beneficiary deductibles and coinsurance amounts. Chapter 6 evaluates beneficiary satisfaction with the program, and Chapter 7 evaluates whether the CAP has had any impact on beneficiary access to drugs covered under the CAP. Chapter 8 considers physician satisfaction. Chapter 9 summarizes the evaluation findings to date, and outlines areas for future research.

CHAPTER 2
RANGE OF VENDORS AVAILABLE TO CAP-PARTICIPATING PRACTICES

One of the mandated subjects of this evaluation report is the range of CAP vendors available to CAP-participating practices. Although multiple vendors participated in the bidding process, and contracts were offered to all bidders who met program requirements and were in the competitive range, only BioScrip signed a contract to become an approved CAP vendor. While not part of the original program design, participation of a single vendor in the competitive acquisition program may not represent an unsatisfactory choice for CAP-participating practices. This analysis suggests that the business model conforming most to the legislated program design, specialty pharmacy, is a highly concentrated industry with relatively few firms capable of fulfilling the requirements of the CAP. Since there were multiple CAP vendor bidders, the payment amount reducing effects of competition at the bidding stage may in part still be realized. Also, anticipating a gradual building of physician election in this program, having a single vendor may have allowed the vendor to be able to recoup the costs of developing the required billing and customer support systems better than if the early volume were divided among multiple vendors. Furthermore, thus far BioScrip appears to have been capable of servicing the additional volume while providing the full range of CAP drugs.

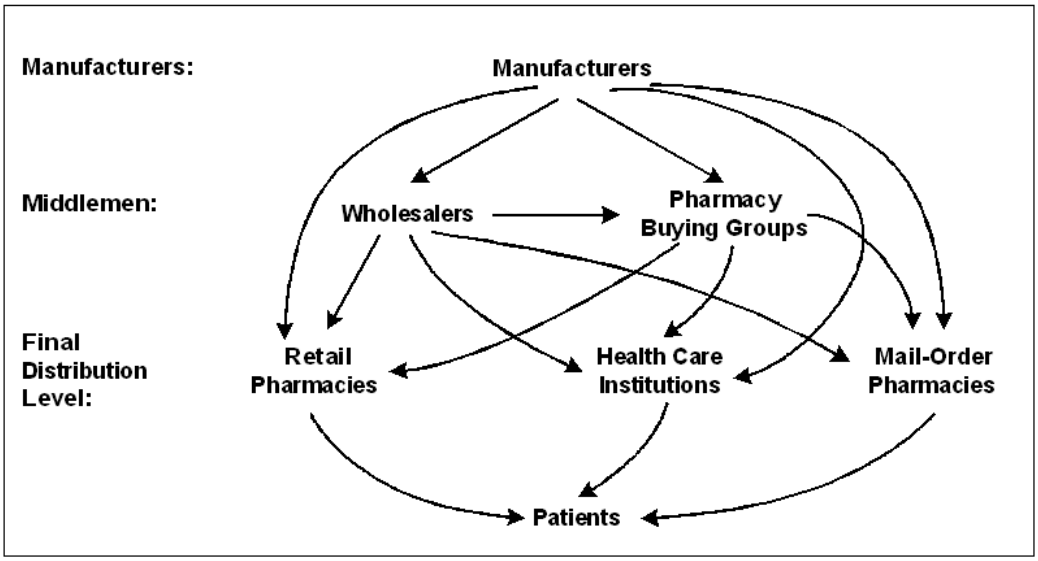
Because only one bidder signed a contract to provide drugs under the CAP, the risk to the CAP program was increased because of potentially poor vendor performance. Were the vendor to have performance problems, physicians and beneficiaries might have associated the problems with CMS rather than the vendor. In addition, the participation of a single vendor eliminated choice within the CAP program. If physicians were unhappy with the vendor, they could not switch vendors. Although there is continued interest in the CAP among physicians, it is impossible to know whether there would have been more interest had there been greater choice of vendors.

This chapter describes the way in which prescription drugs, and particularly the classes of drugs included in the CAP, are currently distributed. This explanation will shed light on the how designation of a single national vendor is workable under competitive acquisition program for these drugs, as well as the implication of that decision.

2.1 The CAP Business Model

Exhibit 2-1 shows the general distribution system for prescription drugs. For simplicity, the distribution chain is divided into three levels: manufacturers; "middlemen," who provide an intermediate stage between manufacturers and the final distribution level; and the final distribution level supplying drugs to patients, either directly or through administration by a physician. In the most traditional Part B drug supply scenario, manufacturers sell drugs to wholesalers, who in turn sell the drugs to physicians, retail pharmacies, or health care institutions, which then administer or distribute the drugs to patients. Recently, entities such as group purchasing organizations (GPOs) and mail-order pharmacies have formed to reduce prices to middlemen and patients. In some cases, the manufacturer may skip the middleman and sell directly to retail or specialty pharmacies, health care institutions, or mail-order pharmacies at the final distribution level. For a physician to be paid for a Part B drug under the standard "buy-and-bill" payment method, the physician must be in the final distribution level.

Exhibit 2-1. Pharmaceutical distribution channels



SOURCE: RTI International.

It is important to note that wholesalers and distributors do not sell drugs directly to patients. In fact, State pharmacy laws generally distinguish between wholesalers and distributors—which can sell drugs only to providers and suppliers (including pharmacies) and to other wholesalers and distributors—and entities able to dispense drugs to patients, including freestanding and provider-based pharmacies and physician offices. The importance of this distinction is emphasized in ***Exhibit 2-2***, which illustrates the flow of payments and drugs under the CAP.

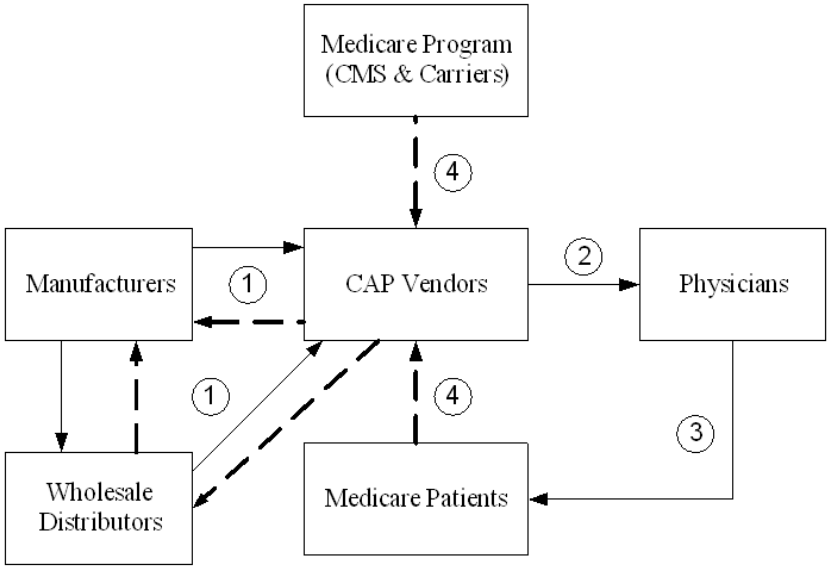
The basic actors in the program are the Medicare program (CMS and its Part B carriers), manufacturers, CAP vendors, physicians, and the Medicare patients. The sequences of drug administrations and payments are as follows, and indicated by the numbers in Exhibit 2-2.

1. **Acquisition of drugs from manufacturers and distributors.** In order to have drugs and biologicals available upon request by physicians, CAP vendors must purchase the products they contractually agreed to provide from the various pharmaceutical manufacturers and wholesale distributors.[18] Drugs flow from manufacturers and distributors to the CAP vendors, and payments[19] flow from the vendors to the manufacturers and distributors.

18 However, if a vendor acquires a drug or biological from a distributor, that distributor must have acquired that product directly from the manufacturer according to Section1847B(b)(4)(C)(i) of the Social Security Act, as amended by Section 303(d)(2) of the MMA.

19 The flows of drugs and payments between vendors and manufacturers will not likely literally be simultaneous; vendors will presumably have standard commercial payment terms (e.g., payment within 30 days).

Exhibit 2-2. Flows of drugs and payments under the CAP



NOTE: Solid lines represent the flow of drug products, and dashed lines represent the flow of payments for those drugs.

SOURCE: RTI International interpretations of Section 303(d)(2) of the MMA and discussions with CMS.

2. **Delivery of drugs from CAP vendors to physicians upon physician order.** Physicians participating in the CAP submit an order for a drug for a particular patient for a certain number of treatments, and the CAP vendor ships the drug to the physician. Also, the CAP vendor will send information to CMS or the relevant carrier(s) that the drug was ordered for the patient and shipped to the physician. Importantly, the CAP vendor does not sell the drug to the patient; the drug remains the property of the vendor until it is administered.

3. **Administration of the drug to the patient.** After receiving the drug from the vendor, the physician (after performing any necessary mixing, compounding, or other preparation to the drug) administers the drug to the patient. The physician then submits a bill for the drug administration procedure and information on the drug that was administered to the relevant Medicare Part B carriers. Note that physicians cannot bill the Medicare program or beneficiaries for the drug itself when participating in the CAP. It is at this point that the vendor provides and furnishes the drug to the patient.

4. **Payments made to vendors.** In the original specification of the CAP, in the MMA, after CMS and the Part B carriers receive a claim for a CAP drug administered to a patient, it was matched against the information provided by the CAP vendor about the

prescription. Upon verifying the information, the Medicare program paid the vendor, and the vendor then billed the beneficiary and supplemental insurer for co-insurance and any deductible amounts. Under the revised system mandated by the MEIA-TRHCA, most CAP vendor claims are paid upon their receipt by the designated carrier. The vendor also bills the beneficiary and supplemental insurer for applicable cost sharing amounts. As legislated in the MMA, vendors cannot collect applicable deductible and co-insurance amounts until the drug has been administered. In addition, the MEIA-TRHCA required CMS and its contractors to conduct post-payment review of vendor claims to ensure that payments to CAP vendors based on claims submitted upon receipt of an order are appropriate.

The fact that the CAP vendor is directly providing the drug to the patient generally bars a holder of a wholesale/distribution license, and not a pharmacy license, from being a CAP vendor.[20] Thus the CAP, as mandated by law, fits the pattern of a pharmacy model. Specialty pharmacies, as described in the next section, are clearly the most likely—if not only—existing organizational/business model able to meet the legislated CAP requirements on a national basis.

2.2 Description of the Specialty Pharmacy Industry

Understanding how the specialty pharmacy field developed and currently functions provides the necessary context in which to understand how a single national CAP vendor is a reasonable policy option. Beginning in the 1970s, a subset of the traditional pharmacy industry was created with the advent of home intravenous (IV) pharmaceutical suppliers. This subset of pharmacy suppliers offered IV parenteral nutrition and IV antibiotics that were less expensive and more convenient than providing these drugs in hospitals. Between the 1970s and the mid-1990s, the home IV pharmacy industry expanded rapidly, and profit margins for these pharmacy suppliers fell (Pharmaceutical Care Management Association, 2007). By 1995, the home IV pharmacy market began to evolve to focus on providing injectable drugs for patients with chronic diseases such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, hemophilia, multiple sclerosis, cystic fibrosis, and immune deficiencies. These suppliers are generally known as specialty pharmacies.

Generally, specialty pharmacies focus on drugs not administered orally or with special storage and handling requirements. Many, though certainly not all, are injectable drugs (whether administered subcutaneously, intramuscularly, intravenously, or intravitreally). Some can be self-administered (e.g., interferon α-2a, α-2b), but many must be administered under a doctor's or nurse's direct supervision. Many of these specialty drugs require special handling including short periods before product expiration and strict temperature controls. Unlike retail pharmacies and many physicians who work infrequently with these complex drugs, specialty pharmacies have the capability to manage these complex products through economies of scope in ordering and managing the products in high volumes, allowing for proper handling and administration. Furthermore, and importantly, specialty pharmacy suppliers, being pharmacies, can sell drugs directly to patients.

20 Of course, a wholesaler/distributor can participate in a joint venture with a pharmacy to be a CAP vendor. As discussed in Section 2.2, several large specialty pharmacies are business units or subsidiaries of large drug distributors.

In 2005, specialty pharmacy expenditures totaled nearly $40 billion, about 20 percent of the total prescription drug market. In recent years, nationwide expenditures on specialty pharmacy services have grown by about 22 percent per year, disproportionately faster than other segments of the pharmaceutical industry (Namovicz-Peat, 2007).

The four largest specialty pharmacy suppliers are: (1) CuraScript, a subsidiary of Express Scripts, a pharmacy benefit management (PBM) company; (2) AmerisourceBergen Specialty Group, a subsidiary of Amerisource Bergen, a pharmaceutical distributor and supplier; (3) Accredo Health Group, a subsidiary of MedCo, a PBM; and (4) Caremark Specialty Pharmacy, a subsidiary of CVS Caremark, a retail pharmacy and distribution company. Together, these four firms account for nearly 80 percent of the specialty pharmacy industry. ***Exhibit 2-3*** displays the major specialty pharmacy suppliers and their annual revenues in 2006. In 2006, BioScrip, the eighth largest specialty pharmacy supplier by gross revenue, had $689 million in annual revenues, or 1.79 percent of the specialty pharmacy market.

Furthermore, Exhibit 2-3 demonstrates that the specialty pharmacy industry is fairly concentrated, making selection of a single national vendor less restrictive than it might appear. To measure market concentration, the Department of Justice and the Federal Trade Commission uses the Herfindahl-Hirschman Index (HHI). The HHI takes into account the relative size and distribution of the firms in a market and approaches zero when a market consists of a large number of firms of relatively equal size. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases. Decreases in the Herfindahl index generally indicate a loss of pricing power and an increase in competition, whereas increases imply the opposite. As shown at the bottom of Exhibit 2-3, the specialty pharmacy market has an HHI of 2,066, labeling it as "concentrated".[21] For comparison, the HHI for the airline industry in 2001 was estimated to be 1,180 (Rubin and Joy, 2005); for research pharmaceutical manufacturers in the 1990s, 2,160 (Danzon, Nicholson, and Pereira, 2005); for Medicare Advantage plans in 2002, 5,600 (Scanlon, Swaminathan, and Chernew, 2004); and for commercial HMOs in 2002, 3,584 (Scanlon, Swaminathan, Chernew, and Lee, 2006).

However, all specialty pharmacy suppliers do not provide a uniform range of services. A number of specialty pharmacy suppliers, including some of the largest ones, provide only a limited set of drugs, mostly for chronic diseases and not all drugs used for treating these diseases. Some specialty pharmacies focus on home infusion, respiratory, and other drugs generally administered through an item of durable medical equipment. In addition, a number of specialty pharmacies offer chronic disease management-type services, including performing retrospective reviews, compliance monitoring, and refill management. A review of a number of specialty pharmacy Web sites suggests that their mail order and home infusion services are intended for direct shipment to patients. Several specialty pharmacies mention shipment of drugs directly to physician offices.

21 Markets in which the HHI is between 1,000 and 1,800 are considered to be moderately concentrated, and those in which the HHI is in excess of 1,800 are considered to be concentrated. Transactions that increase the HHI by more than 100 points in concentrated markets presumptively raise antitrust concerns under Section 1.5 of the Horizontal Merger Guidelines issued by the U.S. Department of Justice and the Federal Trade Commission.

Exhibit 2-3. Specialty pharmacy supplier annual revenues and market shares, 2006

Company	2004 annual revenues ($ millions)	Market share (% of total revenues)
Express Scripts/CuraScript	$ 14,126	36.71 %
AmerisourceBergen Specialty Group	7,400	19.23
Accredo Health Group	5,400	14.03
Caremark Specialty Pharmacy	3,500	9.10
Walgreens Health Services Division	2,600	6.76
PharmaCare Management Services, Inc.	1,300	3.38
McKesson Specialty Pharmaceutical	800	2.08
BioScrip	689	1.79
Florida Infusion Services, Inc.	478	1.24
Option Care, Inc.	402	1.04
Curative Health Services	286	0.74
Apria Healthcare Group	256	0.67
IVPcare, Inc.	160	0.42
Diplomat Specialty Pharmacy	120	0.31
Lincare Holdings	105	0.27
Chartwell Diversified Services, Inc.	100	0.26
Crescent Healthcare	95	0.25
Advanced Care Scripts	80	0.21
MOMS Pharmacy	70	0.18
BioPlus Specialty Pharmacy Services	55	0.14
Cardinal Health Specialty Pharmaceutical Services	50	0.13
ICORE Healthcare, Inc.	50	0.13
Vital Care	45	0.12
HomeCall Pharmaceutical Services	44	0.11
Commcare Pharmacy	40	0.10
NMHC	33	0.09
Axium Healthcare Pharmacy	30	0.08
IVSolutions	25	0.06
BioFusion, Inc.	25	0.06
WellPoint NetRx	24	0.06
PediaMed Pharmaceuticals	21	0.05
Partners Rx Management, LLC (PRx)	13	0.03
Biologics	13	0.03
Burman's Specialty Apothecary LLC	13	0.03
Factor Support Network Pharmacy	13	0.03
Advanced Pharmacy Solutions	11	0.03
Medex BioCare	4	0.01
Total Revenues	$ 38,477	
Hirfendahl-Hirschman Index (HHI)		2,066

SOURCE: AIS Health 2Q2007 quarterly survey of pharmacy benefit management companies (AIS Health, 2007).

2.3 Summary

Given the current concentration of the specialty pharmacy marketplace, and the relatively limited range of competitors capable of fulfilling all CAP vendor requirements, the utilization of a single vendor, Bioscrip, appears to be a reasonable policy outcome. Though CAP-participating physicians could choose only BioScrip, to date there is no evidence of systematic problems in access to drugs or beneficiary satisfaction (see later chapters for more discussion on these evaluation issues). BioScrip is a specialty pharmacy supplier with two primary business lines. First, and largest with respect to total revenue, is their Specialty Services business, which includes: (1) local distribution of specialty pharmacy drugs through community pharmacies; (2) mail distribution of drugs to patients or physician offices, generally under contract with a managed care organization; and (3) infusion services. According to BioScrip's 2006 Annual Report, BioScrip claims to be able to provide "traditional and specialty medications," but primarily focuses on specialty pharmacy services for patients with the following chronic conditions: (1) cancer; (2) Crohn's disease; (3) hemophilia; (4) hepatitis C; (5) HIV/AIDS; (6) immune deficiencies; (7) multiple sclerosis; (8) organ transplants; and (9) rheumatoid arthritis. BioScrip also offers PBM services not generally confined to specialty pharmaceuticals.

Relative to the overall size of BioScrip's Specialty Services business, the CAP constitutes a relatively small proportion. According to BioScrip's quarterly 8-K filings with the Securities and Exchange Commission (available on the SEC EDGAR Web site), total revenue for specialty pharmacy services in the nine months ended September 30, 2007 was $717.5 million. Over the same period, BioScrip reported that their total revenue from the CAP was $30.8 million, or 4.3 percent.

CHAPTER 3
COMPARISON OF PAYMENT AMOUNTS UNDER THE CAP VERSUS 106 PERCENT OF AVERAGE SALES PRICE

One important, if not the most important, source of potential cost savings, or cost increases, of the CAP is the deviation between the CAP payment amount and 106 percent of the average sales price (ASP). This is the sum of the program payment plus beneficiary deductibles and coinsurance amounts for Part B drugs paid under Section 1847A of the Social Security Act (so-called "buying-and-billing"). CMS based the current CAP payment amounts for most CAP drugs on the medians of the bids submitted by the four acceptable bidders. For weighted drugs, these payment amounts were restricted so that the "composite bid," the sum of bid amounts weighted by the bidding weights,[22] did not exceed 106 percent of the October 2005 average sales prices.[23] The bidding weights, in turn, were computed as the proportions of HCPCS units for each CAP drug among total HCPCS units for these drugs (administered by a physician in an office setting) in 2004. Thus, the calculated median of the composite bids can be viewed as an expected average payment amount for CAP drugs, estimated in 2005 prior to any knowledge of actual utilization of these drugs, administered by physicians participating in the CAP. However, the true average payment amount actually realized once physicians began acquiring CAP drugs from the CAP vendor, may differ from this expected value if the actual utilization patterns among physicians in CAP-participating practices differ from those among all Part B drug-administering physicians.

Although CAP composite bid payment amounts were required to be at or below 106 percent of the ASP in place at the time the bidding process was established, a few factors may have contributed to a *de facto* excess of CAP payment amounts over 106 percent of ASP. First, in setting payment amounts under the CAP, CMS applied an inflation factor based on the Producer Price Index (PPI) for prescription drugs in order to adjust payment amounts from the bids made in 2005 to payment amounts in 2006. Since the composition of the CAP "basket" of drugs differs from that used for the PPI, it is possible that the ASPs for CAP drugs lagged inflation in drug prices overall. Chapter 4 of this report compares actual CAP payment amounts to estimates of what they would have been had the PPI-based inflation adjustment not been made.

To assess the differences between CAP payment amounts and fees based on 106 percent of the ASP, this chapter first compares CAP payment amounts to 106 percent of ASP fees in effect during 2006 on a drug-by-drug basis. The CAP payment amount for a particular drug may differ from 106 percent of the ASP for a given point in time for two main reasons. First, for drug

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22 As noted in Chapter 1, the bidding weights were set equal to the sum of the HCPCS units of the 169 CAP drug HCPCs provided in 2004 in physician offices, divided by the sum of the HCPCS units for all of those drugs.

23 As noted in Chapter 1, CAP prices for the 169 HCPCs that bidders were required to bid on were based on the median bid, with an adjustment to compensate for changes in acquisition costs. CAP prices for new drugs added to the CAP drug list were set to 106 percent of ASP in the quarter in which the drugs were added. The 169 CAP drug HCPCS codes used in the bidding process are referred to as "weighted" CAP HCPCs, and other CAP drug HCPCs, including the additional HCPCS codes comprising the remainder of the 182 HCPCs covered at the beginning of physician use of the CAP system, are referred to as "new" CAP drug HCPCs.

payment amounts based on the composite bid, bids may have been above or below the average value of 106 percent of ASP based on fees *at that time* (early 2005). Second, between 2005 and 2006 ASPs for each drug changed, and CAP payment amounts were updated uniformly using the Producer Price Index (PPI), not individual ASP changes. Thus, to analyze CAP versus 106 percent of ASP payment amount differences, this chapter begins with an analysis that compares the difference between these payment amounts on a drug-by-drug basis, then constructs a "price" index to compare average CAP payment amounts and 106 percent of ASP for the aggregate "bundle" of drugs administered by physicians in CAP-participating practices.

3.1 Methods

The data used in this analysis are 2006 Carrier claims with at least one HCPC matching one of the 185 CAP HCPCs for 2006[24] with an administration date between July 1 and December 31, 2006. This analysis compares actual costs of the CAP program with a hypothetical cost in each of the two latter quarters of 2006; because this analysis does not compare across time periods, any seasonality in utilization of these drugs should not affect this comparison. However, any other effects of seasonality that might affect changing composition of drugs administered over the year were not considered in this analysis since it was based on six months of data and not an entire year. The data were restricted to claims with a CAP modifier indicating normal CAP acquisition (with a J1 modifier attached to the CAP drug HCPC) or restocking of a drug administered in an "emergency" (both a J1 and a J2 modifier attached to the CAP drug HCPC). Drugs administered under the "Furnish as Written" provision, for drugs with a specific formulation not available from the approved CAP vendor, were excluded since payments for these drugs are set on the basis of 106 percent of ASP.

Denied CAP drug claim lines were excluded, with the exception of lines with a processing indicator of "O" (other denial reason). CAP drug line items with the "other denial reason" code were retained since nearly one-third of CAP drug line items submitted by physicians in CAP-participating practices (the corresponding percentage for CAP drugs administered by non-electing practices is 2.4 percent), and during initial implementation there were some incorrect billing practices by CAP physicians.[25] These claims have been going through the post-payment review process mandated by the MEIA-TRHCA legislation. As a result, at the time of the writing of this report, the extent to which some, many, or all of these claims will be, in fact, denied is not known. However, given the number of "O" denials, it is reasonable to expect that some will pass the review process and be allowed. Examples of incorrect billing include not applying the correct billing modifiers (based on analyses of the claims, this seems to have affected less than 0.1 percent of claim line items, though); not including the CAP order number on the claim (potentially a larger problem); or possibly other

24 Originally, CMS included 182 Part B drug HCPCs in the CAP (not 182 distinct drugs since some drugs, such as cyclophosphamide, have multiple HCPCs for different package sizes, concentrations, or formulations). For the fourth quarter of 2006 CMS added three HCPCs to the list BioScrip was required to provide, based on CMS's authority to add certain single-indication orphan drugs, for a total of 185. For 2007, four HCPCs were dropped (two based on HCPCS coding changes and two based on deemed appropriateness for the CAP), and four were added (one new drug and three based on HCPCS coding changes), for a total of 185 CAP HCPCs for 2007.

25 As a result of these incorrect billing practices, CMS and Noridian Administrative Services hosted several presentations focusing on educating physicians on correct billing practices.

issues such as misidentifying Medicare as a secondary payer. Although these claims have a special denial code applied by the Carrier, there is no evidence that beneficiaries did not receive needed drugs or that beneficiaries have experienced, or may experience additional financial liability associated with this denial code. Some of these claims will be evaluated during the post payment review process, and if these claims are denied, then neither the beneficiary nor Medicare will be financially liable.

After creating the dataset of CAP drugs administered either through the CAP or outside of the CAP, CAP payment amounts and 106 percent of ASP fees from January 2006 to April 2007 were merged by HCPCS code. Although claims from CAP-participating physicians only during the period during which they participated in the CAP in 2006 (spanning at most the July 1, 2006 to December 31, 2006 period) are used in this analysis, ASPs from periods before and after are used to estimate time trends for predicting future ASPs.

Indications for each CAP drug were identified using the 2007 edition of *Drug Facts and Comparisons* (Wolters Kluwer Health, 2006). Drugs were identified as "single source" if, in the HCPCS-NDC crosswalk file associated with CMS's quarterly ASP data releases, only NDCs from a single manufacturer are associated with a HCPCS code.

3.2 Overall Findings

In 2006, 129 of the 182 available CAP drugs were administered to Medicare beneficiaries under the CAP program. Based on Medicare claims with dates of service between July 1 and December 31, 2006 processed through the National Claims History File as of April, 2007, total Medicare program payments plus beneficiary payments (sum of HCPCS units multiplied by CAP payment amounts, equivalent to allowed charges) for CAP drugs in 2006 are shown in ***Exhibit 3-1***. On average, during 2006, the cost of drugs administered through the CAP exceeded 106 percent of ASP by approximately 3.5 percent. Since CAP drug payment amounts were set so, that, on average, assuming the mix of Part B drugs administered through the CAP would be the same as the mix of all Part B drugs, CAP payment amounts would not exceed 106 percent of ASP, assuming ASPs for CAP drugs rose at the same rate as the PPI for prescription drugs. Thus these findings indicate that physicians electing the CAP do not administer the same mix of Part B drugs as do physicians not participating in the CAP. However, without a direct cross-sectional comparison between CAP and non-CAP physicians this cannot be empirically shown.

Exhibit 3-2 disaggregates the average excess of 3.5 percent of CAP payment amounts over 106 percent of ASP by whether the CAP payment amount for the drug exceeds 106 percent of ASP. Regardless of whether the drug was in fact administered in 2006 under the CAP, a large majority (about 75 percent) of individual CAP drugs have CAP payment amounts exceeding 106 percent of ASP. For drugs with CAP payment amounts exceeding 106 percent of ASP, the unweighted average excess is about 19 percent, and for drugs with CAP payment amounts less than 106 percent of ASP, the unweighted average difference is about 10 percent. Because the overall CAP volume-weighted excess of CAP payment amounts over 106 percent of ASP is 3.5 percent, this suggests that the highest-cost CAP drugs have relatively modest differences between CAP payment amounts and 106 percent of ASP fees.

Exhibit 3-1. Total 2006 CAP drug cost (program plus beneficiary payments), by quarter

Quarter	Cost using CAP payment amounts ($ thousands)	Alternative cost using ASP+6% payment amounts ($ thousands)	CAP cost ÷ alternative ASP+6% cost (%)
Allowed CAP drug line items only			
2006Q3	$ 1,134.4	$ 1,099.0	103.2%
2006Q4	2,426.8	2,343.4	103.6
Total	$ 3,561.2	$ 3,442.4	103.5
Allowed and "other denial" CAP drug line items			
2006Q3	$ 1,611.2	$ 1,559.3	103.3%
2006Q4	3,113.9	2,995.7	103.9
Total	$ 4,725.1	$ 4,554.9	103.7

NOTE: Although the extent to which the "O" denial claims will be, in fact, allowed is not possible to determine at this time, it is reasonable to expect that some will become allowed claims.

SOURCE: RTI International analysis of claims submitted by physicians in CAP-participating practices, payment amounts for drugs administered through the CAP (claims submitted and processed in the CMS National Claims History File as of April, 2007), and third and fourth quarter of 2006 ASPs. Cost using CAP payment amounts imputed using units of service reported in claims data multiplied by CAP payment amounts.

Exhibit 3-2. Excess of CAP payment amounts over/under 106 percent of ASP, by whether CAP payment amount exceeds 106 percent of ASP

	CAP drugs administered under the CAP in 2006		All CAP drugs†	
CAP payment amount greater than/less than ASP+6%?	Number of HCPCs	Unweighted average excess of CAP payment amount over ASP+6% (%)	Number of HCPCs	Unweighted average excess of CAP payment amount over ASP+6% (%)
Greater Than	97	+19.18 %	131	+18.85 %
Less Than or Equal to	32	−10.16	46	−8.13

NOTES: (†) The number of "All CAP Drugs" in this table sums to 177 rather than 182 since 5 HCPCs for lyophilized cyclophosphamide (J9093–J9097) did not have ASPs published during the second half of 2006 (due to drug availability).

SOURCE: RTI International analysis of claims submitted by physicians in CAP-participating practices, payment amounts for drugs administered through the CAP, and third and fourth quarter of 2006 ASPs.

3.3 Factors Associated with CAP Payment Amounts Differing from 106 Percent of ASP

Although, in 2006, the cost of drugs acquired through the CAP on average exceeded what the cost would have been had those drugs been paid at 106 percent of ASP, it is not the case for each CAP drug. ***Exhibit 3-3*** displays the top 30 highest-cost (within the CAP, allowed and "other denial" line items only), and ***Exhibit 3-4*** displays the 30 most frequently-administered (number of claims on which the HCPCS code appears) CAP drugs.

All but six of the 30 highest total-cost drugs administered under the CAP, accounting for 95 percent of the total cost of all allowed CAP utilization in 2006, have CAP payment amounts exceeding 106 percent of ASP. Daptomycin (brand name Cubicin, an IV antibiotic used to treat complicated skin and structure infections as well as septicemia) is the CAP drug with the highest total CAP cost that also has a CAP payment amount less than 106 percent of ASP. It is the 14th most costly, in total, CAP drug, accounting for 1.09 percent of total CAP cost. The six CAP HCPCs among the 30 highest total cost with CAP payment amounts lower than 106 percent of ASP account for only 4.4 percent of the 95 percent of CAP costs accounted for by these 30 CAP drug HCPCs. The percentages by which the CAP payment amounts of the other drugs in this list exceed 106 percent of the ASP are less than six percent.

Exhibit 3-4 displays the 30 most frequently-administered (based on claim volume) drugs acquired through the CAP. The CAP payment amounts for 25 of these 30 drugs exceed 106 percent of ASP, mostly by 1 to 6 percent (two drugs, ceftriaxone sodium and carboplatin, have CAP payment amounts three to five times the 106 percent of ASP fee, but percentages this high are anomalies). For example, in late 2005, ceftriaxone sodium (J0696) went off patent, and its ASP dropped from approximately eight dollars per 250 mg to about two dollars for the same quantity. Because CAP bidding occurred in 2005, when this drug was still on-patent, and HCPC-specific adjustments to CAP payment amounts for "weighted" drugs were not made, the CAP payment amount for this drug turned out to be well above 106 percent of its ASP. Ultimately, such anomalies also balance out against the rest of the CAP drug payment amounts.

To understand additional characteristics associated with the excess of the CAP payment amount over 106 percent of ASP, linear regressions of the natural logarithm of the ratio of the CAP payment amount to the 106 percent of ASP fee for each CAP drug were estimated. The explanatory variables were: (1) indicators for each of 21 groups of indications; (2) the natural logarithm of the annualized CY2006 total cost (allowed charges, so Medicare program costs plus beneficiary cost sharing) of that drug from administration in physician offices (including both drugs administered through the CAP and through the customary "buy-and-bill" practice); and (3) an indicator for whether the drug is single source. Because the annualized total cost of the drug is, by construction, associated with CAP payment amounts (since the cost of drugs administered through the CAP are included), the model that uses the cost of the drug was estimated using the "buy-and-bill"-only cost of the drug as an instrument, under the assumption that utilization of these drugs outside of the program is not affected by whether the CAP payment amount for a particular drug is higher or lower than 106 percent of ASP.

Exhibit 3-3. Top 30 CAP drugs and ratio of CAP payment amount to 106 percent of average sales price, by CAP cost

HCPCS code	HCPCS description	2006 CAP cost	2006 CAP cost percent of total (%)	2006 CAP payment amount ($)	2006 Average ASP+6 % ($)	Percent excess CAP payment amount over ASP+6% (%)
J1745	INJECTION INFLIXIMAB, 10 MG	$ 1,643,786	34.79 %	$ 56.10	$ 54.06	3.78 %
J9310	RITUXIMAB, 100 MG	375,819	7.95	478.75	478.27	0.10
J0885	INJECTION, EPOETIN ALFA (FOR NON-ESRD USE), 1000 UNITS	367,460	7.78	9.67	9.38	3.14
J0881	INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)	306,823	6.49	3.15	3.00	4.97
J2505	INJECTION, PEGFILGRASTIM, 6 MG	299,018	6.33	2,182.61	2,158.01	1.14
J9035	INJECTION, BEVACIZUMAB, 10 MG	220,330	4.66	59.97	56.88	5.43
J2357	INJECTION, OMALIZUMAB, 5 MG	214,405	4.54	16.68	16.53	0.93
J9263	INJECTION, OXALIPLATIN, 0.5 MG	115,455	2.44	8.95	8.77	2.06
J9170	DOCETAXEL, 20 MG	102,369	2.17	308.34	302.18	2.04
J9355	TRASTUZUMAB, 10 MG	92,730	1.96	57.10	56.06	1.85
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG	71,834	1.52	210.04	203.69	3.12
J9201	GEMCITABINE HCL, 200 MG	65,591	1.39	121.69	121.36	0.27
J9055	INJECTION, CETUXIMAB, 10 MG	61,969	1.31	52.25	49.86	4.79
J0878	INJECTION, DAPTOMYCIN, 1 MG	51,400	1.09	0.31	0.32	–3.15
J2503	INJECTION, PEGAPTANIB SODIUM, 0.3 MG	49,839	1.05	1,107.54	1,054.70	5.01
J2469	INJECTION, PALONOSETRON HCL, 25 MCG	46,299	0.98	18.89	18.21	3.73
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG	42,568	0.90	293.57	297.65	–1.37
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG	36,392	0.77	183.80	197.91	–7.13
J9206	IRINOTECAN, 20 MG	35,983	0.76	133.27	126.88	5.04
J9305	INJECTION, PEMETREXED, 10 MG	33,869	0.72	42.71	42.54	0.41
J9041	INJECTION, BORTEZOMIB, 0.1 MG	33,426	0.71	30.47	31.88	–4.41
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG	30,766	0.65	73.78	69.66	5.92
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG	30,572	0.65	8.73	1.71	409.89
J7320	HYLAN G-F 20, 16 MG, FOR INTRA ARTICULAR INJECTION	25,922	0.55	209.05	198.70	5.21
J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG	23,339	0.49	186.71	187.40	–0.37
J9350	TOPOTECAN, 4 MG	22,458	0.48	802.06	809.26	–0.89
J3396	INJECTION, VERTEPORFIN, 0.1 MG	21,451	0.45	9.40	8.92	5.36
J0585	BOTULINUM TOXIN TYPE A, PER UNIT	21,429	0.45	5.15	5.03	2.33
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG	20,944	0.44	4.03	3.71	8.58
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG	20,271	0.43	382.48	377.91	1.21

NOTES: CAP Cost is the product of HCPCS units of the drug administered under the CAP multiplied by the total CAP payment amount (Medicare program cost plus beneficiary deductible and coinsurance).

SOURCE: RTI International analysis of claims submitted by physicians in CAP-participating practices and payment amounts for drugs administered through the CAP.

Exhibit 3-4. Top 30 CAP drugs and ratio of CAP payment amount to 106 percent of average sales price, by CAP frequency of administration

HCPCS Code	HCPCS description	CAP claims on which HCPC appears	All CAP claims (%)	2006 CAP payment amount ($)	2006 Average ASP+6 % ($)	Excess CAP payment amount over ASP+6% (%)
J2912	INJECTION, SODIUM CHLORIDE, 0.9%, PER 2 ML	3,525	31.08 %	$ 0.12	$ 0.11	4.35 %
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS	2,881	25.41	0.05	0.05	6.42
J7050	INFUSION, NORMAL SALINE SOLUTION, 250 CC	2,667	23.52	0.27	0.26	5.29
J0885	INJECTION, EPOETIN ALFA, (FOR NON-ESRD USE), 1000 UNITS	1,041	9.18	9.67	9.38	3.14
J3370	INJECTION, VANCOMYCIN HCL, 500 MG	1,005	8.86	3.35	3.30	1.40
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG	886	7.81	9.96	9.31	6.93
J1745	INJECTION INFLIXIMAB, 10 MG	850	7.50	56.10	54.06	3.78
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG	772	6.81	8.73	1.71	409.89
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1 MG	549	4.84	0.11	0.14	–21.72
J0881	INJECTION, DARBEPOETIN ALFA, 1 MICROGRAM (NON-ESRD USE)	543	4.79	3.15	3.00	4.97
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG	396	3.49	8.11	8.02	1.10
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10MG	366	3.23	1.14	1.12	2.22
J0878	INJECTION, DAPTOMYCIN, 1 MG	338	2.98	0.31	0.32	–3.15
J9260	METHOTREXATE SODIUM, 50 MG	314	2.77	1.91	2.41	–20.84
J2357	INJECTION, OMALIZUMAB, 5 MG	300	2.65	16.68	16.53	0.93
J1200	INJECTION, DIPHENHYDRAMINE HCL, UP TO 50 MG	296	2.61	0.75	0.73	2.24
J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML=1 UNIT)	289	2.55	0.55	0.51	7.14
J2469	INJECTION, PALONOSETRON HCL, 25 MCG	245	2.16	18.89	18.21	3.73
J3420	INJECTION, VITAMIN B-12 CYANOCOBALAMIN, UP TO 1000 MCG	244	2.15	0.31	0.31	−0.29
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS	243	2.14	0.13	0.11	13.85
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG	186	1.64	73.78	69.66	5.92
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG	178	1.57	4.03	3.71	8.58
J1756	INJECTION, IRON SUCROSE, 1 MG	156	1.38	0.37	0.36	1.65
J9035	INJECTION, BEVACIZUMAB, 10 MG	153	1.35	59.97	56.88	5.43
J2010	INJECTION, LINCOMYCIN HCL, UP TO 300 MG	146	1.29	3.70	3.77	−1.81
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG	145	1.28	293.57	297.65	−1.37
J9310	RITUXIMAB, 100 MG	141	1.24	478.75	478.27	0.10
J2505	INJECTION, PEGFILGRASTIM, 6 MG	137	1.21	2,182.61	2,158.01	1.14
J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG	123	1.08	186.71	187.40	−0.37
J9045	CARBOPLATIN, 50 MG	115	1.01	37.01	9.63	284.36

NOTES: CAP Cost is the product of HCPCS units of the drug administered under the CAP multiplied by the total CAP payment amount (Medicare program cost plus beneficiary deductible and coinsurance). Restock of Emergency-Administered Percent is the percentage of allowed utilization for which physicians billed for restocking a drug not previously ordered. HCPCs J2912 (sodium chloride injection 0.9% per 0.2 mg) and J1642 (heparin sodium lock flush per 10 units) are no longer CAP drugs because of concerns about the appropriateness of these drugs for the CAP.

SOURCE: RTI International analysis of claims submitted by physicians in CAP-participating practices and payment amounts for drugs administered through the CAP.

Two models were estimated: one using only the indication group indicators and one using those plus the other regressors. The first model basically computes the average CAP payment amount excess, adjusting for the fact that many drugs may have multiple indication groups. The second model also indicates whether single-source drugs (available only from a single manufacturer) have a greater CAP payment amount excess and whether the CAP payment amount excess is associated with whether a drug is generally high total cost to the Medicare program and Medicare beneficiaries. Specifically, the latter explanatory variable is the total cost of the drug administered by physicians not participating in the CAP. This group of physicians, rather than physicians participating in the CAP, was used to determine total program plus beneficiary cost of the drug to prevent endogeneity bias in the coefficient estimate. The indicator of whether a drug is single-source was included to determine whether the approved CAP vendor, because it must provide these drugs, would have a pricing disadvantage for drugs with only one manufacturer (that would likely have monopoly pricing power).

The results in ***Exhibit 3-5*** suggest that there are few characteristics strongly associated with CAP payment amounts exceeding 106 percent of ASP. Among drug indications, only rheumatologic drugs tend to have CAP payment amounts significantly exceeding 106 percent of ASP. However, from Exhibit 3-3, we note that the most frequently-administered, and most costly, rheumatoid arthritis drug, infliximab, has a CAP payment amount exceeding 106 percent of its ASP by 3.9 percent. Thus the CAP payment amount excess over 106 percent of ASP is for lower-volume rheumatoid arthritis drugs.

Exhibit 3-5. Decomposing factors associated with CAP payment amount excess over 106 percent of ASP

Variable	Number in category	Model 1: Indication groups only				Model 2: Adding single-source & ASP-based cost			
		Coefficient estimate	Std. Err.	*t*	*p*-value	Coefficient estimate	Std. Err.	*t*	*p*-value
Constant		0.066	0.050	1.320	0.188	0.023	0.133	0.170	0.864
Log(ASP+6% Cost)						0.006	0.010	0.650	0.517
Single Source	57					−0.096	0.051	−1.900	0.060
Indication									
Allergy	16	−0.078	0.187	−0.420	0.677	−0.072	0.187	−0.380	0.702
Antidote	6	0.019	0.113	0.170	0.864	0.024	0.113	0.210	0.830
Cancer	82	−0.020	0.053	−0.370	0.711	−0.030	0.054	−0.560	0.573
Cardiovascular	29	0.052	0.079	0.660	0.509	0.045	0.079	0.570	0.572
Dermatologic	17	−0.236	0.136	−1.730	0.086	−0.209	0.140	−1.490	0.138
Diluent	3	0.005	0.153	0.030	0.974	−0.030	0.153	−0.190	0.848
Endocrine	27	0.081	0.075	1.090	0.279	0.089	0.075	1.200	0.233
Gastrointestinal	20	−0.017	0.102	−0.170	0.868	−0.006	0.102	−0.060	0.953
Hematologic	26	−0.054	0.074	−0.740	0.463	−0.069	0.075	−0.920	0.357
Infections	29	−0.017	0.057	−0.300	0.765	−0.023	0.060	−0.390	0.699
MS	16	0.035	0.132	0.270	0.790	0.047	0.132	0.360	0.719
Muscle Relaxant	7	−0.071	0.115	−0.610	0.540	−0.101	0.116	−0.870	0.384
Nausea	7	0.023	0.127	0.180	0.855	0.012	0.127	0.100	0.923
Nutrition	9	−0.042	0.095	−0.440	0.661	−0.039	0.095	−0.410	0.683
Ophthalmologic	17	0.019	0.119	0.160	0.873	−0.004	0.120	−0.040	0.972
Other Urological	2	0.000	0.183	0.000	0.998	0.020	0.182	0.110	0.912
Pain	5	0.136	0.123	1.110	0.271	0.134	0.124	1.080	0.283
Psychiatric	4	0.067	0.142	0.470	0.638	0.060	0.141	0.420	0.674
Respiratory	17	−0.081	0.136	−0.590	0.553	−0.085	0.135	−0.630	0.528
Rheumatologic	21	0.264	0.102	2.570	0.011	0.232	0.105	2.210	0.029
Therapeutic Aid	2	−0.162	0.199	−0.810	0.417	−0.187	0.198	−0.940	0.348
R^2		0.077				0.100			
N		173				173			

NOTES: The regression model using log(Cost), where "cost" is the sum of beneficiary and program expenditures for all claims in 2006 from physicians not participating in the CAP. Regression coefficients are elasticities, which are interpreted as the percentage increase in the CAP versus ASP+6% payment amount difference from a one percentage point increase in total cost to Medicare and beneficiaries of the drug or, if exponentiated and multiplied by 100, as the percent increase in the payment amount difference if a drug has that characteristic. Note that drugs can be assigned to multiple indication groups.

SOURCE: RTI International analysis of claims submitted by physicians in CAP-participating practices and payment amounts for drugs administered through the CAP. Indications are from the 2007 edition of *Drug Facts and Comparisons* (Wolters Kluwer Health, 2006).

3.4 Summary

These findings suggest that, at least in the first six months of the program, CAP payment amounts for drugs actually administered by participating physicians with dates of service between July 1 and December 31, 2006 were higher than under the ASP based alternative. Based on Medicare claims processed through the National Claims History File as of April, 2007, on average (during 2006), the cost of drugs administered through the CAP exceeded 106 percent of ASP by approximately 3.5 percent in the aggregate for 2006. This finding may be subject to change because it reflects the presence of claims that have not been finalized. Furthermore, it should be noted that this finding also does not reflect the average 2.3 percent reduction in CAP payment amounts for the 2008 annual adjustment since claims for 2008 are not yet available. In addition, bidding weights for future rounds of vendor bidding will reflect the mix of drugs ordered by CAP-participating physicians, which was not possible when setting bidding weights for the initial implementation of the program. This may have important impacts on future assessments of differences between CAP payment amounts and 106 percent of ASP fees under a reinstated CAP program.

Since the majority of CAP drug payment amounts were set assuming the mix of Part B drugs administered through the CAP would be the same as the mix of all Part B drugs administered in 2004 and that ASPs would rise at the same rate as the PPI for prescription drugs,[26] CAP payment amounts should not, if these assumptions turned out to have been correct, have exceeded 106 percent of ASP. The indicated use of the drug is not strongly related to whether CAP payment amounts exceed 106 percent of ASP—the primary exception are drugs used for rheumatologic conditions. High- and low-use drugs (measured by total cost to the program and beneficiaries) appear equally likely to have CAP payment amounts above or below ASP. This report's findings, however, only reflect payment amount differences early in the program and prior to the first annual CAP payment amount update. CMS announced that CAP payment amounts for 2008 would average about 2.3 percent less than 2007 payment amounts to account for changes in the net acquisition costs of CAP drugs and ASP-linked payment amount limits.

26 As discussed in Chapter 4 of this report, the average actual ASP for the weighted CAP drugs fell by nearly one percent, whereas the PPI for prescription drugs rose nearly five percent between 2005 and 2006.

CHAPTER 4
ACTUAL & EXPECTED SAVINGS TO MEDICARE AND BENEFICIARIES

The comparisons of CAP payment amounts to fees determined by 106 percent of ASP suggest that, at least early in the first six months of the CAP, there were likely negative program savings as a result of the CAP. Although CAP composite bid payment amounts were required to be at or below 106 percent of the ASP in place at the time the bidding process was established, a few factors may have contributed to a *de facto* excess of CAP payment amounts over 106 percent of ASP. First, in setting payment amounts under the CAP, CMS applied an inflation factor based on the Producer Price Index (PPI) for prescription drugs in order to adjust payment amounts from the bids made in 2005 to payment amounts in 2006. Since the composition of the CAP "basket" of drugs differs from that used for the PPI, it is possible that the ASPs for CAP drugs lagged inflation in drug prices overall. Second, the CAP bidding weights in effect assumed a distribution of utilization of these drugs that may differ from the actual utilization of these drugs by CAP-participating practices.

4.1 Methods

The analysis method in this chapter focuses on the difference between 106 percent of ASP and CAP payment amounts as a measure of the actual and expected savings under the CAP, rather than also including changes in utilization.[27] Physicians began acquiring drugs under the CAP in the second half of 2006, so only six months' claims data were available to analyze for this report. Also, as will be shown in Chapter 8, physician (and non-physician practitioner) participation in the CAP rose throughout 2006 and 2007, from 134 practices (477 unique physicians/practitioners, as identified by UPINs) initially participating in July 2006 to over 750 practices (2,487 unique physicians/practitioners) by early 2007. By the end of 2007, a total of 1,110 practices (3,795 unique physicians/practitioners) have participated in the CAP. [28]

To measure the actual observed impact of differences between CAP payment amounts and ASPs, and to estimate the impact of future payment amounts, a CAP drug "price" index was developed. In particular, a fixed-basket (Laspeyres) price index was created, with weights equal to the relative HCPCS units of each CAP drug HCPCS code administered through the CAP in 2006. This price index was then normalized to 1.0 by dividing the weighted average payment amount by the weighted average value of 106 percent of ASP during the second half of 2006. Specifically, let $p(d,s,t)$ be the payment amount of drug d under payment system $s \in \{\text{ASP,CAP}\}$ in year and quarter t, and let $q(d,\text{ASP},t)$ be the quantity, in HCPCS units, of drug d administered under payment system $s \in \{\text{ASP,CAP}\}$ in year and quarter t. Then the price index is computed as

$$I(s,t) = \sum_{d \in \{\text{CAP Drug}\}} p(d,s,t) w(d), \tag{4-1}$$

27 There was insufficient data for comparisons of cost and utilization between CAP-electing and non-electing physicians to be statistically valid due to the small number of participating physicians. Consequently, CMS was unable to directly compare CAP-electing and non-electing physicians during 2006.

28 Examination of the claims used for this analysis indicated that they were not affected by the post-payment review process that began in April 2007 as authorized by the MEIA-TRHCA legislation.

where the weight $w(d)$ for drug d for computing the price index is given by

$$w(d) = \frac{\sum_{t \in \{2006Q3,2006Q4\}} q(d,\text{CAP},t)}{\sum_{t \in \{2006Q3,2006Q4\}} \sum_{d \in \{\text{CAP Drug}\}} p(d,\text{CAP},t) q(d,\text{CAP},t)}. \quad (4\text{-}2)$$

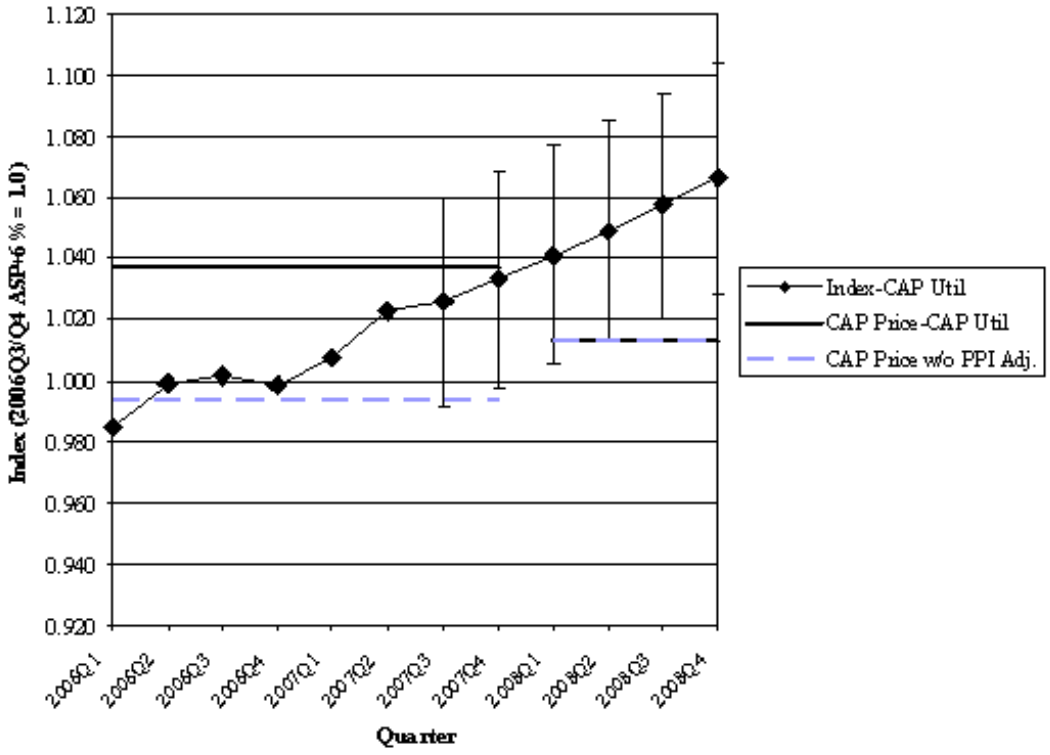
The weight for drug d in Equation (4-2) is computed by summing the quantity of the drug administered in the second half of 2006, then dividing by the total cost of the CAP in the second half of 2006. When substituted into Equation (4-1), the result is a weighted sum of payment amounts for CAP drugs divided by the total CAP cost in the second half of 2006. The quantities of the drug administered in the third and fourth quarters of 2006 are used to compute the numerator of 2006 because we are normalizing by two quarters' cost of the CAP program. Comparing the value of the price index for ASPs versus CAP payment amounts will indicate whether the Medicare program acquisition cost for CAP drugs is higher under ASP pricing or through the CAP.

To measure ASPs in time periods for which data were not available at the time these analyses were conducted, time trends in the ASP for each CAP drug HCPCS code were estimated using a linear regression. The data for these regressions were extracted from the January 2006 through October 2007 ASP files. The ASPs for each CAP HCPCS code were regressed on a constant and a count of the number of quarters since 2006Q1. The resulting regression models were used to compute predicted ASPs for each CAP HCPCS as well as the prediction error of that estimated ASP, used to compute the prediction error of the ASP price index values. Because the time trends are computed using nearly two years of price data, they should average out any seasonality in price changes for these drugs that may exist.

4.2 Estimating Changes in Actual and Expected Payments Using a CAP "Price Index"

Exhibit 4-1 presents the estimated "CAP Drug ASP+6% Index" for the first quarter of 2006 through the end of 2008 (the end of the current CAP vendor contract). The two solid horizontal lines (at 1.037 in 2006 and 2007 and at 1.013 in 2008) shows the average payment amount of CAP drugs in these time periods, relative to the average level of 106 percent of ASP for these drugs in the second half of 2006 (this relative average payment amount is the value of the price index for CAP drugs acquired through the CAP). The thin line with diamond-shaped symbols gives the actual and predicted values of the 106 percent of ASP CAP drug index, with error bars indicating 95 percent confidence intervals for the predicted index values. All throughout 2006 and 2007, CAP payment amounts exceeded ASPs for CAP drugs by between 0.4 percent and 3.7 percent (these percents are computed by expressing the difference between the CAP payment amount index and the 106 percent of ASP index as a percentage). The largest differences occurred in 2006, the first six months of physician participation in the CAP, and this difference fell over time throughout 2007.

Exhibit 4-1. ASP+6% CAP price index actual values and predictions



NOTES: ASP+6% Price Index computed by computing a weighted average of 106 percent of ASP fees using the proportion of the HCPCS units of a particular drug provided under the CAP between July 2006 and December 2006 with respect to the sum of HCPCS units for all drugs administered under the CAP (normal CAP billing and emergency restocking only). Solid points represent index values using actual 106 percent of ASP fees, and open points represent index values computed using HCPCS-specific time trend projections of 106 percent of ASP fees. Error bars indicate the 95 percent confidence intervals of the prediction error of the time trend projections. The ASP+6% Price Index is normalized to 1.0 for the July through December, 2006 (3Q/4Q 2006) period. Actual CAP payment amounts relative to 106 percent of ASP fees relative to the average for the 3Q/4Q 2006 period are shown with the two solid lines (due to lower drug acquisition costs, CMS reduced CAP payment amounts by an average of 2.4 percent for 2008). Hypothetical CAP payment amounts, under the counterfactual that CAP payment amounts were not updated between 2005 and 2006 using the change in the PPI for prescription drugs, are shown in the dashed line.

SOURCE: RTI International analysis of CAP payment amounts and 106 percent of ASP fees.

For 2008, CMS adjusted CAP payment amounts for changes in the vendor's acquisition cost, resulting in an average reduction in CAP payment amounts of about 2.3 percent.[29] The result on the CAP price index is shown as the solid horizontal line for 2008. Based on the HCPC-specific time trend regressions, the average value of 106 percent of ASP for CAP drugs is now expected to exceed the CAP payment amount by between 2.8 percent and 5.3 percent (rising over time) during 2008.

The results of this time series analysis suggests that, for the entire 30-month period of the initial CAP contract, the program will be approximately budget-neutral. During 2006 and 2007, CAP payment amounts on average exceeded 106 of ASP for CAP HCPCS. However, this difference fell over time contemporaneously with increasing physician practice participation in the CAP (see Chapter 8). Furthermore, although CAP payment amounts are expected to be, on average, less than 106 percent of ASP for only four of the 10 quarters of the first CAP contract, if current trends in ASPs for CAP drugs continue, the program savings will rise over time.

Recall that, in setting initial CAP payment amounts, CMS adjusted (upward) the median bids for the 169 (at the time) "weighted" CAP drugs from mid-2005 to mid-2006 using the PPI for prescription drugs. This decision, set in regulations in July 2005, resulted in an increase in the CAP payment amounts for these drugs of nearly five percent from 2005 to 2006. However (not shown in Exhibit 4-1), the average ASPs for these drugs actually fell by nearly one percent for the same period. Because CMS stated in 2005 that it would update bids by the PPI for prescription drugs, when it turned out that the change in the average payment amount for these drugs was significantly lower than the PPI increase, CMS could not ignore the previously-set policy. The impact of the PPI update is shown as the difference between the 106 percent of ASP index line and the dashed line, which displays the hypothetical CAP payment amount index had no PPI update been made. Were CMS not to have updated the bids by using the PPI, the CAP would be predicted to always have reduced expenditures for the program and for beneficiaries rather than only in 2008.

These predictions depend on some critical assumptions. Most important is the implied assumption that CAP volume will be constant over the 30-month period. However, since the number of physicians in CAP-participating practices has nearly doubled from about 1,800 to over 2,800, one would expect CAP order volumes to increase. To the extent that order volume is higher in later than in earlier years, the CAP program's savings would increase. Another critical assumption is that the relative volumes of each CAP drug are fixed over time—if the increase in the number of CAP-participating physicians and practices changes the composition of CAP

29 CMS reduced CAP prices for the 165 "weighted" drugs—those HCPCS codes with prices based on competitive bidding, excluding the two drugs that were dropped from the CAP and the two HCPCS codes that were reorganized into four separate codes—by approximately 2.4 percent. CAP prices for the remaining drugs—with prices based on 106 percent of ASP at the time of introduction into the CAP—were revised upwards or downwards to reflect recent acquisition costs. For CAP prices in CY2008, CMS used its authority under Section 1847B(c)(7) of Title XVIII of the Social Security Act to make a price adjustment during the CAP contract period based on evidence of an approximately 2.4 percent lower acquisition cost relative to the vendor's initial bid. CMS calculated these costs from the quarterly reporting on drug acquisition costs that the vendor is required to make.

orders, the actual CAP expenditures may vary markedly from the predictions shown in Exhibit 4-1.

4.3 Summary

In summary, this analysis on six months' data projects that for the first 18 months of physician participation in the CAP, CAP payment amounts, on average, will exceed 106 percent of the ASPs for CAP drugs.[30] This was the result of a critical decision made in 2005, prior to knowledge of subsequent changes in ASPs, to update CAP payment amounts for the CAP drugs with payment amounts based on competitive bidding using the PPI for prescription drugs. Had these payment amounts not been updated, the CAP would have reduced Medicare program and beneficiary expenditures on these drugs. However, over the full 30-month period of the first CAP vendor contract, it is expected that the CAP will be approximately budget neutral because of estimated, based on linear time trends[31] of prior ASPs, average increases in the ASPs for these drugs and because of the recent downward adjustment to CAP payment amounts for the vendor's lower acquisition costs. Beneficiaries receiving CAP drugs from a CAP-participating practice for this entire period would likely not be materially financially affected, positively or negatively, by the CAP. Beneficiaries receiving drugs through the CAP in 2006 and 2007 likely had co-insurance payments for these drugs between 0.4 percent and 3.7 percent higher than would have been the case had their physician's practice not elected to participate in the CAP. The highest likelihood of CAP payment amounts exceeding ASP payment amounts occurred early in the program. In contrast, beneficiaries who receive CAP drugs from CAP-participating practices in 2008 will likely experience coinsurance payments three to five percent lower than beneficiaries who do not receive CAP drugs from a CAP-participating practice. This is due in part to estimated increases in ASPs (assuming pre-existing price trends continue into 2008) and in part to the 2.3 percent average CAP payment amount reduction in the annual adjustment for 2008.

30 Claims data are only available for 2006; program savings estimates assume that average quarterly CAP volume in 2007 equals that for the third and fourth quarters of 2006. Since CAP participation rose in 2007, a period when program savings deficits were smaller than in 2006, it may be that actual program savings deficits in 2007 are smaller than reported in this chapter, or even in fact savings surpluses. This analysis includes the "other denial" claims with final payment subject to the MEIA-TRHCA post-payment review process.

31 Forecasting future ASPs by projecting forward linear trends of prior ASPs may yield significant error in some cases, especially for drugs with expiring patents. However, since predicting future prices for those drugs is very difficult, this report uses linear time trends for simplicity and ease of understanding potential biases.

CHAPTER 5
CHANGES IN COST SHARING

Another theoretical impact of the CAP on Part B drugs relates to the potential for reductions in beneficiary cost sharing. In theory, if the CAP program results in lower payment amounts to Medicare, then beneficiaries who pay a percentage of those payment amounts in cost sharing would also realize lower costs.

Potential reductions in cost sharing can be detected in a few ways. First, the analysis that compares payment amounts of the two alternative Part B payments systems—CAP versus 106 percent of ASP—found that, overall, there were few savings resulting from the CAP program relative to the standard 106 percent of ASP payment in 2006 during the beginning of the program. To the extent that few savings to Medicare were realized, we can then attribute few reductions in cost sharing to beneficiaries as these two are directly related. In addition, to the extent that beneficiaries have supplementary insurance that covers cost sharing, even if changes in cost sharing may have occurred, there would be a minimal impact on beneficiaries' out-of-pocket expenditures on these drugs.

A second method of detecting reductions on cost sharing can be accomplished by investigating beneficiary perspectives. It is possible that, for some beneficiaries, changes in cost sharing were detected. There changes could result from a few different sources. One source is actual reductions in cost sharing due to lower Medicare payment amounts. However, as noted above, there is little evidence for this in comparing the CAP and ASP-based payment amounts. Another source of beneficiary cost sharing impact could result from some systematic change in likelihood that beneficiaries will be charged their co-insurance. During CMS outreach to key stakeholders during the development of the CAP, selected physician specialty associations alleged raised concerns that a third party vendor would be less likely to forgive co-insurance payments (through a charity care program) than would physicians (Greenwald, Drozd, Burton, and Healy, 2005). CMS investigation in early CAP development work did not result in any specific evidence that forgiveness of co-insurance was a common practice among physicians. The issue is being examined further through the physician survey (fielded and analyzed in 2008; results were not available in time to be included in this report). The report on the physician survey will be completed in early Spring, 2009 and will be available at that time. Only one report is required by statute, so an additional report will not be formally submitted to Congress. In lieu of the results of this survey, this report analyses trends in physician participation and usage of CAP drugs as proxy measures.

A series of one-on-one interviews with beneficiaries elicited the perspectives of three patients of CAP-participating physicians on a range of questions about their experiences receiving CAP drugs.[32] Beneficiaries in the four sites where we conducted interviews reported few changes in co-insurance, aside from limited observations that there was now "more paperwork." This is attributable to the fact that most of these beneficiaries (in fact all of the aged beneficiaries) reported having some form of supplemental insurance that covered their co-insurance for the CAP drugs. An additional explanation is that some of notifications these received regarding changes in the process of collection of co-insurance (for example, receiving a

32 The methodology for the one-on-one beneficiary interviews is described in more detail in Chapter 6.

Medicare Summary Notice from the CAP vendor or CAP Fact Sheets distributed by their physician) as "paperwork." Most of these beneficiaries were at most vaguely familiar with BioScrip (the vague familiarity may be due to reading the letter recruiting them for the study). None reported being newly responsible for co-insurance they were not charged for in the past, though none of the beneficiaries could state specifically the amounts of co-insurance they were charged. Beneficiaries we interviewed reported having co-insurance covered either by a Medigap plan, a retiree supplemental policy or Medicaid. Therefore, there was no evidence that there were any changes in co-insurance caused by the CAP, aside from changes tied directly to the changes in the CAP versus ASP-based rates. If most beneficiaries, as observed in the beneficiary interview study, have some form of supplemental coverage that pays co-insurance for Part B drugs it is highly unlikely that any reductions (or increases) will be directly observed by beneficiaries.

CHAPTER 6
PATIENT SATISFACTION

One policy concern related to the implementation of the CAP centered around potential negative impacts on Medicare beneficiaries. In theory, negative impacts affecting beneficiary satisfaction could include less convenient scheduling, potential delays in treatment from physicians not receiving ordered drugs in a timely manner, patient confusion, difficulties associated with co-insurance billing from the approved CAP vendor, and increased claims-related paperwork for beneficiaries.

6.1 Beneficiary Satisfaction Analysis Methods

To replace the originally proposed beneficiary survey (canceled due to CMS funding issues), a series of beneficiary one-on-one interviews were conducted. The goal of the interviews was to determine whether patients of physicians who were participating in the CAP had experienced any inconvenience, difficulty in access, and satisfaction issues related to their physician's participation in the CAP. The interviews were conducted one-on-one, and were relatively unstructured. In some cases, a caregiver, child, or other support individual observed. Because the beneficiary population of interest to this study is likely to be undergoing treatment for a serious illness, conducting focus groups were expected to not be a successful strategy. In general, focus groups are successful when information of a general nature is desired, and interaction among participants yields discussion that brings out that general response. However, in this case, only a set of fairly narrow experiences of beneficiaries related to only certain aspects of their overall medical care was of interest—in a large group, beneficiaries would be more likely to want to discuss their overall care and treatment, and not be confined to the specific issues of access to Part B drugs and vendor billing issues. In addition, beneficiaries with significant health issues may be hesitant to discuss details of their care and prescription drug history in a group setting. Also, particularly in regard to the vendor billing issues, a caregiver may be necessary to respond to questions about these details.

By their nature, beneficiary interviews have limitations. While summaries of the interviews can highlight patterns (or lack of patterns) observed, it is not possible to test for statistical significance. Furthermore, as with any data collection of this type, the healthiest (relatively speaking) of the potentially eligible group are most likely to participate.

6.2 Developing a Sample Frame for Interviews

For these interviews, beneficiaries were recruited from list of appropriate candidates (those receiving one or more CAP drugs from a physician whose practice elected to participate in the CAP and while the practice was participating in the CAP). Candidates were identified using claims submitted by CAP-participating physicians from the 2006 National Claims History (NCH) file. "CAP claims" were defined as those with a service date between the providing physician's practice's start date in the CAP and December 31, 2006 and with a CAP HCPCS code. Claim line items identified as "Furnish-as-Written" (with the J3 modifier) and therefore billed by the physician ("buy-and-bill") rather than through the approved CAP vendor were excluded when constructing the list of beneficiaries receiving one or more CAP drugs.

The beneficiary interviews were conducted in four areas selected as those with the greatest number of Medicare beneficiaries receiving CAP drugs in the second half of 2006. These four areas were: Fort Myers, Florida; Jacksonville, North Carolina; Morgantown, West Virginia; and Circleville, Ohio. Twelve beneficiaries were recruited for interviews in each site; however, given the relatively poor health status of these beneficiaries, potential cancellations were anticipated, and alternatives were sought when possible. Each participant was provided an incentive of $175. This incentive was somewhat larger than typical focus group incentives, which are typically around $75, reflecting the belief that these beneficiaries would be more difficult to attract to an interview. Interviews in each site were conducted in one day (scheduled between 7:30 AM and 9:00 PM), and were videotaped. Participants were provided an informed consent form to sign (retaining one copy). Interviews were conducted by a facilitator (Jeff Henne of The Henne Group) and observed by RTI staff (either Leslie M. Greenwald or Edward M. Drozd).

A total of 48 study candidates were recruited and confirmed, resulting in 40 completed interviews. In each site, there were participants who cancelled on the day of the study due to either their own poor health or the poor health of a spouse or other relative and also because of concerns about the legitimacy of the study. The latter group was much smaller than the first, numbering only three previously-confirmed beneficiaries.

6.3 Site-Specific Findings

6.3.1 Jacksonville, North Carolina

Beneficiaries interviewed in Jacksonville, North Carolina were receiving a range of Part B drugs, including anti-inflammatories, antibiotics, anti-emetics, and corticosteroids. Most beneficiaries at this site are patients of internal medicine physician groups. The beneficiaries reported receiving Part B drugs during either a single office visit, or over a limited (a few months) episode. One beneficiary reported receiving intravenous anti-inflammatories on a monthly basis. Beneficiaries interviewed at this site included a mix of Medicare beneficiaries with supplemental insurance or were dually-entitled to Medicare and Medicaid.

Beneficiaries reported no specific problems with receiving physician administered drugs. One beneficiary's physician reportedly told the beneficiary to return to the office at a later date to actually receive the treatment because the physician "would have to order the drugs." In this case, the visit was scheduled in about one week and this caused no inconvenience to the beneficiary. From the beneficiary discussions, it was not clear which drug was ordered nor why the drug was not obtained more quickly and therefore may not reflect on the CAP. If the physician did not have the required drug in their stock at all, even the Emergency Restocking provision of the CAP would not have helped this beneficiary; furthermore, if this were the case, the beneficiary would need to return for another visit if the physician were not participating in the CAP. Alternatively, the physician may not have been aware of the Emergency Restocking provision, suggesting a need for further physician education (which CMS and Noridian have done in numerous "Ask the Contractor" teleconferences). Others also reported having to return to the physician office to receive drugs, but were not sure why they had to come for an additional visit; they also reported no inconvenience or sense of delayed treatment. One beneficiary who was receiving regularly scheduled monthly treatments for "a few years now" reported no changes. In this extended treatment instance, the beneficiary reported that "[her] doctor always

made sure he had the medicine I needed." One participant reported having problems getting coverage for intravenous saline, but believed this was a coverage issue. The interviews could not determine whether any of these reported multiple office visits was related to delays in obtaining CAP drugs. It is just as likely that these were clinical decisions. Ultimately, these beneficiaries did not believe their care was in any way negatively affected by having to return to the physician office at a later date to receive treatment.

Most beneficiaries at this site reported no changes in billing, possibly because they had supplemental insurance. This is expected since beneficiaries with supplemental insurance would likely not be billed separately for co-insurance for Part B drugs. However, one beneficiary without supplemental insurance and who received monthly intravenous treatments reported that: "Recently there is much more paperwork. Everyone would have to stop what they were doing. And then you would get separate mail for billing. It used to be all handled on the doctors' bill." She appears to report this as corresponding to the timeframe when her physician may have been participating in CAP (starting for about the last year), though this participant did not specifically cite the approved CAP vendor as the reason for the billing changes and increased paperwork. Another beneficiary reported seeing no bills for Part B drugs at all.

One participant reported knowing the name of the approved CAP vendor, BioScrip. She reported hearing about the approved CAP vendor at her doctor's office as the company that supplies her drugs. She asked her doctor about BioScrip but was told she did not have to worry about it. About half of the participants either had not heard about the approved CAP vendor, or had only a vague recollection ("I saw it on something once"). None of the interviewed beneficiaries reported having any negative experiences related to the approved CAP vendor, or had heard negative things about the vendor from other sources, such as their doctors' offices.

6.3.2 Morgantown, West Virginia

Most beneficiaries in this site are patients of cardiology or internal medicine physician groups. They are receiving a range of Part B drugs including anti-thrombotic agents, cardiac stimulants, IV solution additives, and other hematologics.

Some beneficiaries at this site reported no specific recollection of having received an IV administered drug, though their claims information suggests that they had received prescription drugs via an intravenous preparation. One beneficiary reported requiring injections administered by a physician or nurse every two weeks; she gets these injections at the hospital outpatient department currently and has been getting these drugs for about three years. This participant has always received her provider administered drugs at the hospital outpatient department (there has been no change in site of service). Other participants likely received provider administered drugs in conjunction with a myocardial perfusion scintigraphy scan, other cardiac test, or related to a hospitalization. Therefore, it is plausible that beneficiaries receiving Part B drugs under these circumstances have no separate recollection of these drugs being administered.

All of the beneficiaries interviewed in this area had some form of either supplemental coverage, generally as retirees or through Medicaid. None of these individuals reported paying any co-insurance for Part B drugs out of pocket. They reported no issues with billing for co-insurance, either in general or related to Part B drugs. Only two of the nine beneficiaries even

recognized the name of the approved CAP vendor, BioScrip; neither of these beneficiary participants could give any specifics about the approved CAP vendor and did not identify the company as the one they received any requests for co-insurance.

6.3.3 Circleville, Ohio

Most of the beneficiaries in this area who were interviewed received CAP drugs for ophthalmological conditions. However, one of the seven received a Part B drug for a severe respiratory condition. All of these beneficiaries received either an intravitreal or intravenous injection. With one exception, all of the beneficiaries interviewed reported no changes in Medicare billing or availability of drugs received in their physicians' offices since the second half of 2006. Importantly, all of the beneficiaries reporting no billing problems had supplemental insurance that fully covers co-insurance for physician services, including Part B drugs. In addition, nearly all of the CAP drugs administered by these beneficiaries' physicians were billed using the emergency restocking provisions, implying that the drug was not ordered prior to administration but instead ordered afterwards to restock supplies.

One of the beneficiaries interviewed, however, had a very different experience from the other beneficiaries, presumably because of his very different circumstances. This beneficiary receives Xolair (omalizumab) on a biweekly basis because of severe asthma and also, unlike for the other beneficiaries interviewed in Circleville, receives Medicare benefits because of disability, not age. This beneficiary also has had billing and drug availability problems, though not necessarily attributable to the approved CAP vendor. This beneficiary is a lower-income individual who was not able to obtain Medicaid or other government-provided assistance both before and after Medicare eligibility. However, a local, private not-for-profit organization offered to, and is, providing him with assistance paying for deductible and co-insurance amounts. Because of this relatively unique situation, however, he has had problems, both with Workers Compensation and Medicare, with bills being sent to the organization paying many of his bills (he thought they were being paid, when in fact, they were not). Complicating this situation is that many insurers, including a number of Medicare carriers, have particular documentation requirements for patients' disease status and clinical need for the drug. As a result of these complications, this beneficiary did report problems with the availability of the drug from his CAP-participating physician. However, upon further questioning, the beneficiary in fact reported that he experienced more problems with the availability of this drug prior to finding this CAP-participating physician and also that working out billing issues was somewhat easier with the approved CAP vendor than under Workers Compensation.

6.3.4 Fort Myers, Florida

The beneficiaries interviewed in Fort Myers had a range of conditions for why they received Part B drugs under the CAP, including ulcerative colitis, rheumatoid arthritis, other arthritic conditions, and cardiovascular conditions. However, a majority of those interviewed received IV antibiotics for severe infections, particularly postoperative wounds infected with MRSA. Those with severe infections typically received daily IV infusions of Cubicin (daptomycin), vancomycin, or cefepime for two to five weeks.

As with the other sites, most of the beneficiaries interviewed were at most vaguely familiar with the approved CAP vendor—although several reported "scrutinizing" their EOBs, it

was mostly to be sure that the services and dates reported on the EOB accorded with their recollections of when they received care from their physicians. All of the beneficiaries who were at most vaguely familiar with the approved CAP vendor also had supplemental insurance that covered their physician services (including Part B drugs).

Two beneficiaries, however, had different experiences, relating in part to the fact that they receive Medicare benefits because of disability and that such beneficiaries (including these two) often do not have supplemental or have less-generous supplemental. One of these beneficiaries received CAP drugs from his physician because of pulmonary emboli and other cardiovascular conditions. This beneficiary reported no problem with drug availability during visits or with billing. In fact, he has been making partial payments to the approved CAP vendor over a period of time to pay his CAP drug bills and has reported no problems (he noted that he found BioScrip to be "very helpful" in making these payment arrangements). The second beneficiary has received Remicaid (infliximab) and methotrexate because of ulcerative colitis. This beneficiary did report problems with billing; however, these seem generally due to transitioning from private disability insurance to Medicare and the subsequent bill rejections and resubmissions to Medicare and to the private disability insurance carrier.

6.4 Summary

The beneficiaries interviewed generally reported few billing problems and drug availability problems associated with the CAP program and with the approved CAP vendor. A few beneficiaries did need to return to the physician's office to receive treatment, which meant rescheduling an appointment one week or so after their previously scheduled appointment. From the information gathered, it was likely that these return visits were clinical decision that could have occurred regardless of CAP physician participation.

Only two beneficiaries reported a billing problem with the approved CAP vendor. One of these came from a beneficiary with a unique Medicare bill-paying situation. Furthermore, this beneficiary noted that he had similar problems when covered under Workers Compensation and that the problems were resolved more quickly with the approved CAP vendor than with other providers and insurers. The billing problems faced by the second beneficiary seemed more due to issues regarding transitioning from private disability insurance to Medicare than with the approved CAP vendor in particular.

In summary, most beneficiaries seemed to be virtually unaffected by their physicians' participation in the CAP and in fact had little or no sense of any changes having occurred that might be attributable to their physicians' participation in CAP. No impact of the CAP on Part B beneficiary satisfaction was detected. Overall, beneficiaries seemed quite unaware of the existence of the approved CAP vendor, including not recalling receiving any information about the CAP or the approved CAP vendor from their physicians. This lack of awareness of the CAP, and the fact that most noticed no change in the process for receiving Part B drugs, supports the finding that there has been likely no systematic change in Part B beneficiary satisfaction attributable to the CAP.

CHAPTER 7
ACCESS TO COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS

During consultations with provider groups and organizations representing the interests of beneficiaries, as well as during initial presentations by CMS introducing the CAP to physicians, a concern often raised was whether beneficiaries would face problems with access to the specific drugs they use and need.

7.1 Methods

To assess whether beneficiaries may have encountered Part B drug access problems as a result of their physician(s) participating in the CAP, two distinct methods were used, each measuring some aspect of potential access problems. One method is the beneficiary one-on-one interviews described in Chapter 6. During the interviews, beneficiaries were specifically asked whether they encountered problems such as rescheduling of visits, or inability to receive the drug altogether, as a result of the drug not being delivered to the physician's office or because the approved CAP vendor refused to supply the drug.

A second method, using Medicare claims data, examines the rate at which physicians in CAP-participating practices (CAP physicians) have relied on the Furnish as Written (FAW) and Emergency Restocking provisions of the CAP. [33] The purpose of the FAW provision is to enable a CAP physician to provide a specific dosage, concentration, or formulation of a drug to a patient when the specific NDC (drug formulation, concentration, package size, and manufacturer) is not available through the approved CAP vendor. Under FAW, CAP physicians must administer a drug from their own inventory and then submit a claim for that drug with the J3 modifier. The physician would be paid 106 percent of ASP for such drugs.

By statute, the purpose of the Emergency Restocking provision is to make drugs available to beneficiaries in urgent situations by allowing the physician to submit an order retrospectively to resupply a drug provided from the physician's own inventory. In particular, as legislated in the MMA and implemented by CMS, physicians are advised to use the Emergency Restocking provision if: (1) the drug is required immediately; (2) the need for the drug could not be anticipated; (3) the CAP vendor would not be able to ship the drug to the physician in a timely manner if an order were placed; and (4) the drug was administered in an emergency situation. If these conditions are met, CAP physicians can administer the drug from their own inventory and then place an order with the approved CAP vendor *ex post facto* to replenish their inventory as a way to provide the necessary drug to the patient in a timely manner. In this situation, the claim line for the CAP drug must contain both the J1 and J2 modifiers. A high rate of the Emergency Restocking provision suggests that the CAP design included a potentially necessary method of averting potential access problems associated with a requirement for a patient specific drug ordering process. This provision could require CAP-participating practices to maintain a stock of drugs at some financial risk. The practices can minimize this financial risk by decreasing their drug inventory as a result of participating in the CAP, but completely avoiding this risk in practices that administer drugs in urgent and changing clinical circumstances is not possible

33 Examination of the claims used for this analysis indicated that they were not affected by the post-payment review process that began in April 2007 as authorized by the MEIA-TRHCA legislation.

because CAP drugs cannot be stocked at a physician's office. However, physicians who provide these drugs generally maintain an inventory of drugs for their non-Medicare patients and for use for new patients who may need the drug administered in an emergency situation. As a result, providing these drugs to their Medicare patients in situations which they deemed to be an emergency may not have been a hardship. However, high rates of use may also signal that the "ordinary" CAP drug acquisition process (relying on a physician placing an order prior to the day when the beneficiary is administered the drug) is infeasible in more than a limited number of circumstances. Whether CAP-participating physicians anticipated maintaining a level of inventory to account for Medicare beneficiaries' utilization (beyond that needed for other patients) when they elected to participate is unknown.

7.2 Beneficiary Perceptions of Impacts on Access to Part B Drugs

As reported in Section 6 of this report, the beneficiaries who participated in the one-on-one interviews reported few drug availability problems associated with the CAP. A few beneficiaries did report needing to schedule an appointment a week or so after their previously scheduled appointment. In only one case could this be attributable to billing issues with the approved CAP vendor delivering the necessary drug (which was caused be a unique situation in which a private not-for-profit organization paid for many of that beneficiary's co-insurance). Another beneficiary reported that their doctor told them that they would have to return to the office to actually receive the treatment because, as reported by this beneficiary, the physician "would have to order the drugs." More information on the specific reason why the drug could not be administered more quickly is not available. In this case, they were scheduled in about a week and this caused no inconvenience to the beneficiary. Others also reported having to return to the physician office to receive drugs, but were not sure why they had to come for an additional visit. These beneficiaries also reported no inconvenience or sense of delayed treatment, and, from the information gathered, it was not clear whether these delays in receiving treatments could have occurred regardless of CAP election.

7.3 Physician Use of Emergency Restocking and Furnish as Written Provisions

CMS, in designing the CAP, anticipated that the emergency restocking and FAW provisions would be used relatively infrequently. However, these two design features of the CAP were intentionally included specifically to improve flexibility for physicians and overall access to drugs. As described above, CMS placed several Congressionally-mandated requirements on the use of the emergency restocking provision, including the immediate, unanticipated need to provide the drug to the beneficiary and potentially reduce the need for additional return visits. Furthermore, as CMS stated in its July 6, 2006 Final Rule, "the 'furnish as written' option is intended to be used only occasionally in limited circumstances where a patient's medical condition requires a particular formulation of a drug at the NDC level—it is not intended to be used in routine situations as a means to circumvent the normal CAP ordering process." However, CMS did not give guidance on how infrequently these provisions were intended to be used.

Exhibit 7-1 presents the percentages of CAP claim line items in 2006 billed under the normal CAP procedures (J1), under Emergency Restocking (J1 plus J2), and under the FAW provision (J3), stratified by the number of claims submitted by a physician in a CAP-participating practice for CAP drugs for each beneficiary. Beneficiaries receiving CAP drugs

Exhibit 7-1. Percentages of claim line items billed under normal CAP, emergency restocking, and furnish as written provisions for CAP patients, by number of CAP claims for each beneficiary

Number of CAP claims	Distribution of patients		Average number of claims for physicians/ practices administering CAP drugs		Ordinary CAP line items (%)		Emergency restocking line items (%)		Furnish as written (FAW) line items (%)	
	Percent (%)	Number	Physicians	Practices	Percent (%)	Number	Percent (%)	Number	Percent (%)	Number
1	59.4%	2,804	133	1,195	20.0%	831	52.5%	2,091	26.7%	1,062
2	18.1	857	168	1,192	37.4	883	31.5	744	31.1	733
3	8.8	415	233	1,124	47.3	853	26.5	477	26.2	473
4	4.0	187	170	848	51.7	652	41.4	569	11.3	155
5–6	3.5	165	139	1,230	56.9	1,004	40.7	791	7.5	146
7–11	3.4	161	180	1,541	44.1	1,870	52.0	2,207	3.9	164
12+	2.8	133	324	1,890	47.7	4,895	50.4	5,175	1.9	197
Total	100.0%	4,722	169	1,225	42.3%	10,988	46.4%	12,054	11.3%	2,930

NOTES: Population consists of patients with claims for CAP drugs submitted by CAP physicians available in the National Claims History as of May 2007 (4,722 patients).

SOURCE: RTI International analysis of Medicare claims submitted by CAP physicians.

only once from a CAP-participating physician in 2006 (59.4 percent of all beneficiaries administered a CAP drug from a CAP-participating physician in 2006) have only 20 percent of their CAP drug claim line items billed under the normal CAP ordering method. As the number of claims for a beneficiary with one or more CAP drugs submitted in 2006 rises, the proportion of the CAP drug line items in those claims billed under the normal CAP procedure (identified as having only a J1 modifier) rises. For beneficiaries with four or more claims with a CAP drug administered by a CAP-participating physician, the proportion of CAP drug line items billed using the normal CAP procedure rises to 50 percent or more. About half of this increase comes from a reduction in the rate of "emergency" restocking, and about half from a reduction in the rate of FAW administration. As the number of CAP drug claims that are submitted increases, the percentage of CAP drug claim line items billed using the FAW procedure (J3 modifier) decreases to a small 2.1 percent for patients with 12 or more CAP drug claims. Note, however, that the rate of the Emergency Restocking provision remains high—patients with seven or more CAP drug claims in 2006 received 40 percent of their CAP drug claim line items billed under emergency restocking. Other than the fact that patients with the greatest numbers of claims with one or more CAP drugs in 2006 were administered by physicians and practices with the greatest CAP drug claim volumes, there does not seem to be a strong relationship between the number of times a patient receives a CAP drug and their providers' CAP volumes. It is important to note that these findings rely on CAP utilization during the first six months of the program during a period when participating physicians may be adjusting to the new program and may not reflect utilization patterns that may emerge over a longer period.

To determine whether certain types of patients have been differentially affected by their CAP physicians' use of the emergency restocking or FAW provisions, each CAP drug line item (each drug administered, even if on the same claim) was assigned to one of the 189 Hierarchical Condition Categories (HCCs; Pope, *et al.*, 2000), ignoring payment model exclusions and

reassignments, based on the line diagnosis code for that CAP drug. HCCs, developed as a major component of risk adjustment for Medicare Advantage plans, are, mechanically, mutually exclusive groups of diagnosis codes. In the Medicare Advantage risk adjustment system, patients are assigned HCCs on the basis of diagnosis codes listed on all Medicare claims in a given year, with some additional hierarchical logic to ignore certain HCCs when others are assigned. Weights are assigned to each HCC, and these are summed to compute an overall score for a beneficiary. In this report, HCCs are used only as a convenient system of mutually exclusive groups of diagnoses for describing the diagnoses for which a patient is receiving a Part B drug. Note that one beneficiary may contribute to multiple HCCs if that patient received Part B drugs for multiple conditions.

Exhibit 7-2 presents the 35 most frequent HCCs, in descending order of frequency, displaying the percentages of claim line items billed under normal CAP procedures, Emergency Restocking, and Furnish as Written. The 35 HCCs shown in Exhibit 7-2 represent over 95 percent of all CAP drug line items submitted by CAP physicians. There is a great deal of variability in the percentages of CAP drug claim line items billed under the normal CAP procedure. HCCs corresponding to infections (e.g., 37, bone/joint/muscle infections/necrosis; 152, cellulitis & local skin infections; 135, urinary tract infections; and 2, septicemia/shock) tend to have low rates of billing using normal CAP procedures (under one-third). For most of these patients, their first few visits receiving CAP drugs are likely unforeseen—a physician is presumably unlikely to know that a patient will visit their office with an infection sufficiently serious to require a certain drug. However, many of these patients receiving IV antibiotics receive regimens lasting at least one week and typically two or more weeks. Although a physician may need to modify a treatment regimen because an infection is resistant to the drug the patient was receiving, it may be that the rate of Emergency Restocking for these drugs was artificially high. Although some of this utilization may not reflect a true clinical emergency, it may also be the result of physicians keeping access to drugs in order to have flexibility to quickly change therapies (drug or dosage, either of which may require modifications to orders and therefore increased use of the Emergency Restocking provision) for unanticipated clinical reasons. In fact, one of the purposes of Congress and CMS including the Emergency Restocking provision was to incorporate flexibility into the program to respond to physicians' clinical decisions regarding the appropriateness of previously ordered drugs based on their patients' clinical presentation at the time of the visit. Examples of drugs with a need for visit-to-visit flexibility, even well into the patient's treatment regimen, include antibiotics and other anti-infectives, epoetin, and steroidal preparations. The very high (98 percent) rate of FAW use for patients with disorders of the spine and vertebral discs may be due to the need for a specific formulation for administration to a particular site (injection into cerebrospinal fluid versus into a vertebral disc).

By contrast, CAP drugs administered for cancers (e.g., 10, breast/prostate/colorectal/other cancers & tumors; 9, lymphatic/head and neck/brain/other major cancers; 181, chemotherapy; and 8, lung/upper digestive tract/other severe cancers) have normal CAP procedure billing rates of nearly 70 percent or higher. Similarly, patients with chronic conditions such as rheumatoid arthritis (HCC 38) and asthma (HCC 110) also have at least two-thirds of their individual instances of CAP drug administration had their claims billed under the normal CAP billing process.

Exhibit 7-2. Percentages of CAP claim line items billed under normal CAP, emergency restocking, and furnish as written provisions for CAP patients, by HCC

HCC	Description	Percent of patients (%)	J1: Normal CAP (%)	J1+J2: Emergency restocking (%)	J3: Furnish as written (%)
37	Bone/Joint/Muscle Infections/Necrosis	11.6 %	34.5 %	61.1 %	4.4 %
152	Cellulitis, Local Skin Infection	8.8	31.8	67.6	0.6
47	Iron Deficiency and Other/Unspecified Anemias and Blood Disease	7.6	45.7	41.6	12.7
38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	6.8	67.6	28.5	3.9
10	Breast, Prostate, Colorectal and Other Cancers & Tumors	6.5	80.1	16.0	3.9
43	Other Musculoskeletal & Connective Tissue Disorders	5.4	12.8	45.2	42.0
9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	4.9	78.1	20.4	1.5
181	Chemotherapy	4.5	68.1	26.5	5.4
8	Lung, Upper Digestive Tract & Other Severe Cancers	4.0	68.3	28.1	3.5
165	Other Complications of Medical Care	3.4	45.1	54.9	0.0
164	Major Complications of Medical Care and Trauma	3.3	34.8	65.2	0.0
135	Urinary Tract Infection	2.9	26.6	73.3	0.1
115	Other Lung Disorders	2.8	33.5	62.2	4.3
39	Disorders of the Vertebrae and Spinal Discs	2.7	0.3	1.4	98.3
166	Major Symptoms, Abnormalities	2.0	14.7	82.2	3.1
110	Asthma	1.7	75.3	10.7	14.0
40	Osteoarthritis of Hip or Knee	1.6	30.5	31.0	38.5
24	Other Endocrine/Metabolic/Nutritional Disorders	1.5	29.0	10.5	60.5
127	Other Ear, Nose, Throat, and Mouth Disorders	1.5	16.8	74.0	9.3
2	Septicemia/Shock	1.3	17.6	82.4	0.0
121	Retinal Disorders, Except Detachment and Vascular Retinopathies	1.2	39.7	29.8	30.5
109	Fibrosis of Lung and Other Chronic Lung Disorders	1.0	28.0	72.0	0.0
5	Opportunistic Infections	0.9	2.1	97.9	0.0
108	Chronic Obstructive Pulmonary Disease	0.9	23.6	66.7	9.8
44	Severe Hematological Disorders	0.8	73.1	25.9	0.9
85	Heart Infection/Inflammation, Except Rheumatic	0.8	16.0	84.0	0.0
120	Diabetic and Other Vascular Retinopathies	0.7	5.7	85.1	9.2
179	Post-Surgical States/Aftercare/Elective	0.6	78.8	17.5	3.8
140	Male Genital Disorders	0.6	21.4	78.0	0.6
113	Viral and Unspecified Pneumonia, Pleurisy	0.6	33.1	63.6	3.2
167	Minor Symptoms, Signs, Findings	0.5	23.9	69.0	7.0
111	Aspiration and Specified Bacterial Pneumonias	0.5	25.0	48.5	26.5
84	Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease	0.5	11.4	85.4	3.3
72	Multiple Sclerosis	0.4	56.2	28.6	15.2
45	Disorders of Immunity	0.4	26.8	70.1	3.1
	All Others	4.7	27.0	54.5	18.5

NOTES: Population consists of patients with claims for CAP drugs submitted by CAP physicians available in the National Claims History as of May 2007 (4,722 patients).

SOURCE: RTI International analysis of Medicare claims submitted by CAP physicians.

7.4 Summary

The beneficiary interviews did not reveal any systematic problems with patients gaining access to drugs they need. Beneficiaries with supplemental insurance were in fact seldom aware of the CAP and the fact that their physicians must order drugs from the approved CAP vendor. Only one or two beneficiaries could identify occasions in which they needed to return for another visit because of drug availability. However, one other beneficiary reported no worse, and in fact better, availability of the Part B drug he uses under the CAP compared with the period before physician acquisition of drugs through the CAP began.

The purpose of the FAW provision was intended to enable a CAP physician to provide a specific dosage, concentration, or formulation of a CAP drug to a patient when the specific NDC (drug, formulation, concentration, package size, and manufacturer) is not available through the approved CAP vendor. Approved CAP vendors must agree to supply at least one NDC within each of the HCPCS codes included in the CAP. Under the FAW provision, when a particular formulation of a CAP drug is not available from the vendor the CAP physician obtains the drug privately and bills Medicare for it under the ASP program just as he or she would for any drug not on the CAP drug list. A high rate of use of the FAW provision may mean that some of the NDCs the vendor has chosen to supply within the CAP may not be the particular formulation of a drug that a CAP physician needs or wants to supply to his or her patients. While there seemed to be relatively high rates (at least compared to CMS's presumed intention of their use as uncommon) of use by physicians of the FAW and Emergency Restocking provisions in the first six months of the program, there is no indication that this demonstrated a problem with beneficiary access to drugs. On the contrary; physicians are invoking an element of the CAP *specifically designed* to prevent access issues. The use of the emergency restocking and Furnish as Written provisions did, ultimately, result in beneficiaries receiving their prescribed drugs.

However, the high use of the Emergency Restocking provision (over one-third of CAP claims in the first six months of the program) could be problematic for other operational reasons. This provision, used most often for infections based on initial data, could require CAP-participating practices to maintain a stock of drugs at some financial risk. The practices can minimize this financial risk by decreasing their drug inventory as a result of participating in the CAP, but completely avoiding this risk in practices that administer drugs in urgent and changing clinical circumstances is not possible because CAP drugs cannot be stocked at a physician's office. However, physicians who provide these drugs generally maintain an inventory of drugs for their non-Medicare patients and for use for new patients who may need the drug administered in an emergency situation. As a result, providing these drugs to their Medicare patients in situations which they deemed to be an emergency may not have been a hardship. This provision helps ensure timely access to these drugs. It may be the case that physicians utilizing the Emergency Restocking provision for multi-week regimens of intravenous antibiotics misunderstood the intention of the Emergency Restocking provision or it could mean that a needed order of a drug did not arrive timely for whatever reason. After the physician determines the patient needs to have the drug administered daily for multiple weeks, the patient's need for the drug may be well anticipated. Thus the higher-than-expected use of the Emergency Restocking provision may not necessarily suggest a potential access problem as much as the process of becoming adapted to a newly implemented program.

CHAPTER 8
PHYSICIAN SATISFACTION

Although further implementation of the CAP program has been postponed as of December 31, 2008, long-term viability of the CAP, when reinstated, may be strongly influenced by physicians' satisfaction with the program. If physicians are dissatisfied with the program, they may opt not to elect the CAP, and future rounds of bidding for CAP vendors will fail to attract bidders.

8.1 Methods

Physicians' satisfaction with the CAP is being measured through a survey of 1,200 physicians whose practices elected the CAP in 2006 or 2007 and 1,200 physicians whose practices did not elect the CAP. This survey, which was fielded in the first half of 2008, (and therefore not available for analysis in time for the results to be included in this mandated report) included questions on why practices did, or did not, elect the CAP; physicians' satisfaction with acquiring drugs under the CAP and under the standard "buy-and-bill" method; and physician demographics and typical drugs administered. Data analyses from this survey will be reported in a separate report.

In lieu of the availability of the results from the physician survey, an alternative method of understanding whether physicians are satisfied with the CAP is analyzing practices' decisions to elect, or not elect, the CAP for 2007, particularly practices that elected the CAP in 2006. This analysis focuses on the practice, not individual physician, since participation in the CAP is at the practice, not individual physician, level. A dataset of CAP-participating practices was created using the CAP election database maintained by Noridian Administrative Services, the CAP Designated Carrier. This database provided practices' number of practitioners, mix of specialties, and dates of participation in the CAP. Data on these practices' total volume of drugs administered under the CAP and frequency of use of the Emergency Restocking and Furnish as Written provisions was extracted from Medicare claims data and merged onto the CAP election data by administering physicians' UPIN and billing identifier.

This dataset was subset to the 402 practices that elected the CAP in July or August of 2006. Then, a logistic regression model identifying characteristics associated with practices opting not to "re-elect" the CAP in 2007 was estimated, under the assumption that opting not to re-elect the CAP is an indicator of dissatisfaction with the program.

8.2 Results

Exhibit 8-1 presents the number of practices and number of physicians/practitioners electing to participate in the CAP for the four election periods for 2006 and 2007 (July and August of 2006, and January and August of 2007). In the first CAP election period, for participating in the program beginning in July 2006, a total of 134 practices (477 unique physicians) elected to participate in the CAP. Nearly 50 percent (65 of 134) were solo practices, and another 29 percent were small (2–5 providers) practices. In August, another 268 practices (1,040 physicians) joined the CAP, and one-half (137) of these were solo practices. Note that these numbers are for all CAP-participating practices, not only those that acquired drugs through the CAP.

Exhibit 8-1. Counts of practices electing the CAP, by participation date and practice size

		Practices				
		Number of physicians/practitioners in practice				
	Number of unique physicians/practitioners	1	2–5	6–13	14+	Total
Electing for Jul.–Dec., 2006	477	65	39	16	14	134
Electing for Aug.–Dec., 2006	1,040	137	85	29	17	268
Not re-electing for Jan., 2007	566	102	55	15	8	180
Newly electing for Jan.–Dec., 2007	1,517	316	127	68	20	531
Electing for Aug.–Dec., 2007	781	109	61	12	10	192
Participating in December 2006	1,536	204	122	47	31	404
Participating in December 2007	3,247	522	255	108	53	938
Total ever participating	3,795	618	307	125	60	1,110

NOTES: The rows in the top panel give the gross flows (positive or negative) into or out of the program for the standard election dates (July 1, 2006; August 1, 2006; January 1, 2007; and August 1, 2007). The numbers of physicians/practitioners participating on December 31, 2006 or 2007 may not equal counts derived from adding and subtracting the gross flows on these data because some practices and clinicians joined or withdrew at dates other than the standard election dates.

SOURCE: RTI International analysis of CAP election data and 2006 Medicare claims for physicians in CAP-participating practices.

There was significant turnover in the practices electing the CAP for 2007. Of the 402 practices that originally elected the CAP, 180 (45 percent) opted not to re-elect the CAP for January 2007. These practices included 566 unique physicians. A majority (102) of the practices dropping the program were solo practices. Half of the solo practices dropped the program. Furthermore, the rate of dropping the program monotonically declined with practice size so that only 26 percent (eight of 31) of the largest practices (with 14 or more providers), dropped out of the program. However, although 180 practices decided not to re-elect the CAP, 531 practices (1,517 physicians) not previously participating decided to elect to participate in the program. Then, for the August to December, 2007 election period, another 192 practices (781 physicians) opted to participate.

Exhibit 8-2 presents the results of estimating the logistic regression model of factors associated with practices opting not to re-elect the CAP. The first two columns give summary statistics (means and standard deviations) for the dependent variable (a binary indicator of not re-electing the CAP) and explanatory variables in the model. The third column gives odds ratios computed from the logistic regression model, and the fourth column gives estimated "marginal effects"—the impact of a change from 0 to 1 in each explanatory variable—on the probability of not re-electing the CAP.

Few characteristics are statistically significantly associated with not re-electing the CAP for 2007. Practices with allergy/immunology specialists or with pulmonologists have significantly lower rates of dropping out of the program. Practices with these specialties have drop-out probabilities nearly 40 percentage points lower than the average practice, and the average practice was 45 percent likely to not re-elect the CAP. Practices with rheumatologists and with

non-physician practitioners (mostly nurse practitioners and physician assistants) were also less likely to drop out. Practices with non-physician practitioners also tend to be the largest participating practices.

Practices with high rates of utilizing the Furnish as Written provision were more likely to drop out of the CAP; increasing from no FAW provision to 100 percent FAW provision (the two most common FAW proportions) increased the CAP drop out likelihood by nearly 33 percentage points. This is to be expected since the use of the FAW provision indicates that the physicians in that practice were not able to order a specific NDC for their drugs from the approved CAP vendor. Practices that were among the original 134 CAP practices were also less likely to drop out of the program for January 2007. These practices were presumably more certain of their desire to participate in the CAP.

8.3 Summary

A significant proportion (45 percent) of the practices participating in the CAP in 2006 opted not to participate in 2007. Although this rate of deciding not to re-elect the CAP may seem large, it is important to note that 2006 was only the first year (in fact the first six months) of physician participation in this program. A number of practices may have elected in 2006 as a "trial" period since they were required to participate for only six months and they may have had a low rate of Part B drug administration. Furthermore, the number of practices electing the CAP in 2007 rose to 938 (representing a total of 3,247 physicians), several times the number participating initially. Although nearly 200 practices (566 physicians and practitioners) opted not to re-elect for 2007, more than 700 practices (nearly 2,300 physicians and practitioners) elected for the first time in 2007. This may indicate potential interest in the program for these practices.

Exhibit 8-2. Estimated impacts of practice characteristics on the likelihood of not re-electing the CAP

	Summary statistics		Logit model coefficients & odds ratios for not re-electing the CAP					Estimated change in probability of not re-electing the CAP			
Variable	Mean	Std. dev.	Estimate	Std. err.	*z*-score	*p*-value	Odds ratio	Estimate	Std. err.	*z*-score	*p*-value
Not Re-Electing for 2007?	0.448	0.498									
Practice Size											
1	0.502	0.501									
2–5	0.308	0.462	0.342	0.305	1.12	0.261	1.408	0.084	0.075	1.12	0.262
6–13	0.112	0.316	0.281	0.481	0.59	0.558	1.325	0.070	0.120	0.58	0.561
14+	0.077	0.267	−0.543	0.680	−0.80	0.425	0.581	−0.126	0.147	−0.86	0.392
Provider Type in Practice?											
Allergy & Immunology	0.254	0.436	−1.901	0.398	−4.77	<0.001	0.149	−0.394	0.063	−6.23	<0.001
Endocrinology	0.020	0.140	−1.057	1.256	−0.84	0.400	0.348	−0.223	0.209	−1.07	0.286
Non-Physician	0.249	0.433	−0.824	0.361	−2.28	0.023	0.439	−0.191	0.078	−2.46	0.014
Oncology-Related	0.060	0.237	−0.033	0.548	−0.06	0.951	0.967	−0.008	0.133	−0.06	0.951
Ophthalmology	0.127	0.333	0.051	0.495	0.10	0.918	1.052	0.013	0.122	0.10	0.918
Primary Care	0.281	0.450	0.043	0.315	0.14	0.891	1.044	0.011	0.077	0.14	0.891
Psychiatry	0.037	0.190	0.254	0.665	0.38	0.703	1.289	0.063	0.166	0.38	0.705
Pulmonology	0.164	0.371	−1.772	0.427	−4.15	<0.001	0.170	−0.354	0.062	−5.71	<0.001
Rheumatology	0.087	0.282	−0.958	0.473	−2.02	0.043	0.384	−0.211	0.088	−2.38	0.017
Other Specialties	0.194	0.396	−0.065	0.356	−0.18	0.856	0.937	−0.016	0.087	−0.18	0.855
No CAP Drugs in 2006?	0.756	0.430	0.491	0.405	1.21	0.226	1.633	0.117	0.093	1.26	0.209
High CAP Administration Rate?	0.025	0.156	0.049	0.854	0.06	0.995	1.050	0.012	0.210	0.06	0.955
CAP Drug Administration Type											
Proportion Normal CAP Method	0.126	0.310									
Proportion Emergency Restocking	0.050	0.188	−0.411	0.866	−0.47	0.635	0.663	−0.101	0.212	−0.48	0.635
Proportion Furnish as Written	0.068	0.240	1.336	0.637	2.10	0.036	3.804	0.327	0.156	2.10	0.036
Elected for July 2006?	0.333	0.472	−0.509	0.247	−2.06	0.039	0.601	−0.122	0.058	−2.11	0.035
Logit Model Constant			0.408	0.522	0.78	0.434					
Pseudo R^2	0.167										
Number of observations	402										

NOTES: ΔPr[Drop] is the change in the probability of not re-electing the CAP, for practices electing for 2006, for a change from 0 to 1 for each explanatory variable, for practices with values for the other characteristics equal to the overall average. A practice with a "high" CAP drug administration rate was defined as one where the number of CAP drugs administered per practice provider exceeded 64 during the period July to December, 2006 (only 2.5 percent of CAP-participating practices had a CAP administration rate exceeding this amount).

SOURCE: RTI International analysis of CAP election data and 2006 Medicare claims for physicians in CAP-participating practices.

CHAPTER 9
SUMMARY OF EVALUATION FINDINGS

In addition to mandating the implementation of the CAP, the Congress also required the Secretary to submit an evaluation of this program. Specifically, the Secretary is required to report on the following issues:

1. The range of choices of contractors available to physicians
2. Comparison of payment amounts for drugs and biologicals under the CAP versus payment amounts determined under methodologies specified by Section 303(c) of the MMA (106 percent of Average Sales Price)
3. Program savings
4. Reductions in cost-sharing
5. Satisfaction of patients whose physicians have elected to participate
6. Access to competitively biddable drugs and biologicals
7. Satisfaction of physicians electing to participate

This analysis uses a data set of CAP claims for drugs administered between July 1, 2006 and December 31, 2006. Some claims included in this analysis were initially denied claims for the period in which the sample was drawn. However, many of these claims were paid in April 2007 when the provisions of Section 108 of the Medicare Improvements and Extension Act of 2006 (MEIA-TRHCA, or Division B of the Tax Relief and Health Care Act of 2006) were implemented, and these claims were resubmitted. The MIEA-TRHCA required CMS to pay unpaid claims from the period July 1, 2006 to March 31, 2007 upon receipt of the claim, and to verify drug administration for claims paid under the MIEA-TRHCA with a post-payment review process. While this report was being written, post payment review on all claims in the sample had not been completed and therefore payment for these claims is not yet considered final. As a result, certain specific aspects of this report which are affected by the percentage of denied claims, including this report's comparison's of total payment for drugs under the CAP and associated comparisons to payment under ASP methodology, current potential program savings, and impact on beneficiary cost sharing amounts may be subject to change. CMS has since announced on September 10, 2008 that it would postpone further implementation the CAP as of December 31, 2008. As of the end of calendar year 2008 availability of drugs through an approved CAP vendor will be suspended until the CAP is reinstated.

9.1 Range of Vendor Contracts

One of the mandated subjects of this evaluation report is the range of CAP vendors available to CAP-participating practices. Although multiple vendors participated in the bidding process, and contracts were offered to all bidders who met program requirements and were in the competitive range, only BioScrip signed a contract to become an approved CAP vendor. While not part of the original program design, participation of a single vendor in the competitive

acquisition program may not represent an unsatisfactory choice for CAP-participating practices. The business model conforming most to the legislated program design, specialty pharmacy, is a highly concentrated industry with relatively few firms capable of fulfilling the requirements of the CAP. Since there were multiple CAP vendor bidders, the payment amount reducing effects of competition at the bidding stage may in part still be realized. Also, anticipating a gradual building of physician election in this program, having a single vendor may have allowed the vendor to be able to recoup the costs of developing the required billing and customer support systems better than if the early volume were divided among multiple vendors. Furthermore, the approved CAP vendor for the initial implementation period appears to have been capable of servicing the additional volume while providing the full range of CAP drugs.

Because only one bidder signed a contract to provide drugs under the CAP, the risk to the CAP program was increased because of potentially poor vendor performance. Were the vendor to have performance problems, physicians and beneficiaries might have associated the problems with CMS rather than the vendor. In addition, the participation of a single vendor eliminated choice within the CAP program. If physicians were unhappy with the vendor, they could not switch vendors.

9.2 Comparison of Payment Amounts

The key source of potential cost savings associated with the CAP is the difference between CAP payment amounts and the payment amounts for the same drugs provided incident to physicians' services under the ASP (or "buy and bill") methodology. ASP payment amounts are set at 106 percent of the average sales price reported by manufacturers to CMS. During the first round of CAP bidding, bidders were required to base their bids on limits calculated from the October 2005 ASP price file. For weighted drugs, bidders could not exceed 106 percent of composite weighted ASP for the drugs in the single CAP category. In other words, these payment amounts were restricted so that the "composite bid," the sum of bid amounts weighted by the bidding weights, did not exceed 106 percent of the October 2005 average sales prices. The bidding weights were computed as the proportions of HCPCS units for each CAP drug among total HCPCS units for these drugs (administered by a physician in an office setting) in 2004. For unweighted drugs, bids on each drug could not exceed 106 percent of that individual drug's ASP. CMS based the payment amounts that CAP vendors receive for each drug on the median of the bids submitted by each bidder offered a CAP vendor contract. For drugs added to the CAP list as vendor-requested additions after the vendor bidding period, CAP payment amounts were set to 106 percent of the ASP in the quarter in which they were added.

The actual average payment amount under the CAP may differ from the calculated median of the composite bids for multiple reasons. First, actual utilization patterns of weighted CAP drugs among CAP-participating physicians differs from those of all Part B drug-administering physicians. When calculating bidding weights (prior to any knowledge of which physicians would participate), CMS used claims data for all physicians administering these drugs. If the physicians who ultimately participated are systematically different, with respect to utilization patterns of these drugs, then the actual average payment amount will differ from the median of composite bids. For example, CAP payments for immunomodulators, particularly infliximab (used predominantly by rheumatologists), accounted for 41 percent of the total payments for the 169 "weighted" drugs, compared to eight percent using assumptions based on

pre-CAP (2004) data. Also, as discussed in the 2005 interim final and final rules, in response to public comments CMS adjusted CAP payment amounts based on the Producer Price Index (PPI) for prescription drugs in order to account for the time period that elapsed between the bidding period and the period in which the payment amounts were to be in effect. Since the composition of the CAP "basket" of drugs differs from that used for the PPI, it is possible that the ASPs for CAP drugs lagged inflation in drug prices overall. This may occur if CAP drugs happen to have a higher frequency of expiring patents than do prescription drugs in general (whether CAP drugs had a higher frequency of patent expiration than did other Part B drugs is not explored in this report).

To assess the differences between CAP payment amounts and fees based on 106 percent of the ASP, the analysis compared CAP payment amounts to ASP-based fees. In particular, whether CAP payment amounts were associated with higher (or lower) total allowed charges for the drug was determined. This finding suggest that, at least in the first six months of the program, CAP payment amounts for drugs administered by participating physicians with dates of service between July 1 and December 31, 2006 were higher than under the ASP based alternative. Based on Medicare claims processed through April, 2007, on average (during 2006), the cost of drugs administered through the CAP exceeded 106 percent of ASP by approximately 3.5 percent. Since the majority of CAP drug payment amounts were set assuming the mix of Part B drugs administered through the CAP would be the same as the mix of all Part B drugs administered in 2004 and that ASPs would rise at the same rate as the PPI for prescription drugs,[34] CAP payment amounts should not, if these assumptions turned out to have been correct, have exceeded 106 percent of ASP. This difference for 2006, at least in the aggregate, can be attributed to the use of the PPI, rather than actual weighted changes in ASPs from 2005 to 2006, to adjust median bid amounts from 2005 to CAP payment amounts in 2006. Also, this finding may be subject to change because it reflects the presence of claims that have not been finalized. CMS has already announced that CAP payment amounts for 2008 will average about 2.3 percent less than 2007 payment amounts to account for changes in the net acquisition costs of CAP drugs and ASP-linked payment amount limits. In addition, bidding weights for future rounds of vendor bidding will reflect the mix of drugs ordered by CAP-participating physicians, which was not possible when setting bidding weights for the initial implementation of the program. This may have important impacts on possible future assessments of differences between CAP payment amounts and 106 percent of ASP fees under a reinstated program.

9.3 Program Savings

The Congress also required the Secretary to evaluate the overall Medicare program savings as a result of the CAP. To address this question, this report analyzed the difference between 106 percent of ASPs and CAP payment amounts (actual or estimated through the end of 2008, when the current CAP contract ends) as a measure of the actual and expected savings under the CAP, rather than also including changes in utilization. A number of reasons underlay this approach. First, physicians began acquiring drugs under the CAP only in the second half of 2006, so only six to twelve months' data would be available to analyze for this report. In addition, the Congressionally-mandated requirement to pay the CAP vendor's claims upon

34 As discussed in Chapter 4 of this report, the average actual ASP for the weighted CAP drugs fell by nearly one percent, whereas the PPI for prescription drugs rose nearly five percent between 2005 and 2006.

receipt and verify drug administration on a post-payment basis implemented on April 1, 2007 will result in some claims being processed, paid, and then retroactively denied. Making inferences about program and beneficiary savings from this early participation period may provide unreliable estimates of the true program and beneficiary savings. There was insufficient data for comparisons of cost and utilization between CAP-electing and non-electing physicians to be statistically valid due to the small number of participating physicians. Consequently, CMS was unable to directly compare CAP-electing and non-electing physicians during 2006.

CAP payment amounts and ASPs in place during this period, however, are known. Therefore, to measure the actual observed impact of differences between CAP payment amounts and 106 percent of ASPs, and to estimate the impact of future payment amounts, a CAP drug "price" index was developed.

In summary, this analysis on six months' data projects that for the first 18 months of physician participation in the CAP, CAP payment amounts, on average, will exceed 106 percent of the ASPs for CAP drugs.[35] This was the result of a critical decision made in 2005, prior to knowledge of subsequent changes in ASPs, to update CAP payment amounts for the CAP drugs with payment amounts based on competitive bidding using the PPI for prescription drugs. Had these payment amounts not been updated, the CAP would have reduced Medicare program and beneficiary expenditures on these drugs. However, over the full 30-month period of the first CAP vendor contract, it is expected that the CAP will be approximately budget neutral. This is based on linear time trend estimates[36] of prior ASPs, average increases in the ASPs for these drugs and recent downward adjustment to CAP payment amounts for the vendor's lower acquisition costs. Beneficiaries receiving CAP drugs from a CAP-participating practice for this entire period would likely not be materially financially affected, positively or negatively, by the CAP. Beneficiaries receiving drugs through the CAP in 2006 and 2007 had co-insurance payments for these drugs between 0.4 percent and 3.7 percent higher than would have been the case had their physician's practice not elected to participate in the CAP. The highest likelihood of CAP payment amounts exceeding ASP payment amounts occurred early in the program. In contrast, beneficiaries who receive CAP drugs from CAP-participating practices in 2008 will likely experience coinsurance payments three to five percent lower than beneficiaries who do not receive CAP drugs from a CAP-participating practice. This is due in part to estimated increases in ASPs (assuming pre-existing price trends continue into 2008) and in part to the 2.3 percent average CAP payment amount reduction in the annual adjustment for 2008.

CMS also investigated an alternative analytic method that would directly compare CAP-electing and non-electing physicians during 2006. However, there was insufficient data for comparisons to be statistically valid due to the small number of participating physicians.

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35 Claims data were only available for 2006; program savings estimates assume that average quarterly CAP volume in 2007 equals that for the third and fourth quarters of 2006. Since CAP participation rose in 2007, a period when program savings deficits were smaller than in 2006, it may be that actual program savings deficits in 2007 are smaller than reported in this chapter, or even in fact savings surpluses.

36 Forecasting future ASPs by projecting forward linear trends of prior ASPs may yield significant error in some cases, especially for drugs with expiring patents. However, since predicting future prices for those drugs is very difficult, this report uses linear time trends for simplicity and ease of understanding potential biases.

9.4 Reductions in Cost Sharing

There was no apparent evidence of systematic change in cost sharing for beneficiaries as a result of the CAP, either from reductions in Part B drug payment rates or through evidence reported by beneficiaries. Analysis of potential beneficiary cost sharing as a result of payment changes in CAP relative to 106 percent of ASP suggested that there were very limited to no savings that resulted from the CAP program relative to the standard 106 percent of ASP payment in 2006. One potential source of beneficiary cost sharing impact could result from some systematic change in likelihood that beneficiaries will actually be charged their co-insurance. However, neither early CAP development work nor interviews with beneficiaries for this analysis suggested that forgiveness of co-insurance was a common practice among physicians either before, or after, CAP implementation.

9.5 Patient Satisfaction

Patient interviews indicated that most beneficiaries seem to be unaffected by their physicians' participation in the CAP and in fact have little or no sense of any changes having occurred that might be attributable to their physicians' participation in the CAP. While a few beneficiaries reported an increase in return appointments necessary to receive drug regimens under the CAP, it was unclear whether these additional visits were related to drug availability or clinical decision. One beneficiary reported better, availability of the Part B drug he uses under the CAP compared with the period before the CAP was implemented. Therefore, from this analysis, there seems to be no detectable systematic negative impact of the CAP on Part B beneficiary satisfaction.

9.6 Access to Competitively Bid Drugs

Two separate analyses assessed whether beneficiaries may have encountered Part B drug access problems as a result of their physician(s) participating in the CAP. One method gathered feedback from one-on-one interviews with beneficiaries whose physicians elected to participate in CAP. During the interviews, beneficiaries were specifically asked whether they encountered problems such as rescheduling of visits, or inability to receive the drug altogether, as a result of the drug not being delivered to the physician's office or because of the approved CAP vendor refusing to supply the drug. While some beneficiaries reported instances of return visits to received drug regimens, these cases were not described as inconveniences, and may simply have been clinical decisions that would have occurred regardless of CAP. The beneficiaries interviewed reported no systematic perceptions of problems getting access to Part B drugs.

A second method, using Medicare claims data, examined the rate at which physicians in CAP-participating practices (CAP physicians) have relied on the Furnish as Written (FAW) and Emergency Restocking provisions of the CAP. Because early claims data were included in this analysis, some of the claims for the drugs administered using the Emergency Restocking provisions of the CAP may not ultimately be determined to be payable by the Medicare program once the post payment review process is complete.

The FAW provision was intended to enable a CAP physician to provide a specific dosage, concentration, or formulation of a CAP drug to a patient when the specific NDC (drug, formulation, concentration, package size, and manufacturer) is not available through the

approved CAP vendor. Approved CAP vendors must agree to supply at least one NDC within each of the HCPCS codes included in the CAP. Under the FAW provision, when a particular formulation of a CAP drug is not available from the vendor the CAP physician obtains the drug privately and bills Medicare for it under the ASP program just as he or she would for any drug not on the CAP drug list. A high rate of use of the FAW provision may mean that some of the NDCs the vendor has chosen to supply within the CAP may not be the particular formulation of a drug that a CAP physician needs or wants to supply to his or her patients. While there seemed to be relatively high rates of use by physicians of the FAW in the first six months of the program (11 percent)—at least compared to CMS's presumed intention of their use as uncommon, there is no indication that this demonstrated a problem with beneficiary access to drugs. On the contrary; physicians are invoking an element of the CAP *specifically designed* to prevent access issues. The use of the emergency restocking and Furnish as Written provisions did, ultimately, result in beneficiaries receiving their prescribed drugs.

The Emergency Restocking provision helps to ensure beneficiaries receive timely access to drugs in urgent situations by allowing the physician to submit an order retrospectively to resupply a drug provided from the physician's own inventory. As legislated in the MMA and implemented by CMS, physicians are advised to use the Emergency Restocking provision if: (1) the drug is required immediately; (2) the need for the drug could not be anticipated; (3) the CAP vendor would not be able to ship the drug to the physician in a timely manner if an order were placed; and (4) the drug was administered in an emergency situation provisions. The high use of the Emergency Restocking provision found in this evaluation (over one-third of CAP claims in the first six months of the program) could be a sign of potential access problems, or it could reflect physicians adapting to when best to use this provision under the newly implemented program. This provision, used most often for infections based on initial data, could require CAP-participating practices to maintain a stock of drugs at some financial risk. The practices can minimize this financial risk by decreasing their drug inventory as a result of participating in the CAP, but completely avoiding this risk in practices that administer drugs in urgent and changing clinical circumstances is not possible because CAP drugs cannot be stocked at a physician's office. However, physicians who provide these drugs generally maintain an inventory of drugs for their non-Medicare patients and for use for new patients who may need the drug administered in an emergency situation. As a result, providing these drugs to their Medicare patients in situations which they deemed to be an emergency may not have been a hardship. It may be the case that physicians utilizing the Emergency Restocking provision for multi-week regimens of intravenous antibiotics misunderstood the intention of emergency restocking or it could mean that a needed order of a drug did not arrive timely for whatever reason. After the physician determines the patient needs to have the drug administered daily for multiple weeks, the patient's need for the drug may be well anticipated.

9.7 Satisfaction of Physicians

Although further implementation of the CAP program has been postponed as of December 31, 2008, the long-term viability of a reinstated CAP may be influenced by physicians' satisfaction with the program. If physicians are dissatisfied with the program, they may not elect to continue to participate in the program, and future rounds of bidding for CAP vendors may fail to attract bidders. Physicians' satisfaction with the CAP is being measured through a survey of 1,200 physicians whose practices elected the CAP in 2006 or 2007 and 1,200

physicians whose practices did not elect the CAP. This survey, fielded in early 2008, included questions on why practices did, or did not, elect the CAP; physicians' satisfaction with acquiring drugs under the CAP and under the standard "buy-and-bill" method; and physician demographics and typical drugs administered. Mandated timing of this report precluded inclusion of the analysis of the physician survey results.

In lieu of the availability of results from the physician survey, an alternative method of understanding whether physicians are satisfied with the CAP is analyzing practices' decisions to elect, or not elect, the CAP for 2007, particularly practices that elected the CAP in 2006. A significant proportion (45 percent) of the practices participating in the CAP in the first six months of the program opted not to participate in 2007. Although this rate of deciding not to re-elect the CAP may seem large, it is important to note that 2006 was only the first six months of physician participation in this program. A number of practices may have elected in 2006 as a "trial" period since they were required to participate for only six months and they may have had a low rate of Part B drug administration. The number of practices electing the CAP by December 31, 2007 rose to 938 (representing 3,247 physicians, several times the number of physicians who participated initially). Although nearly 200 practices (566 physicians and practitioners) opted not to re-elect for 2007, more than 700 practices (nearly 2,300 physicians and practitioners) elected for the first time in 2007. This may indicate potential interest in the program for these practices.

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