Report to Congress

Transitioning Medicare Part B Covered Drugs to Part D

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2005

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Executive Summary

Section 1860D-42 (c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that the Secretary prepare a report that "makes recommendations regarding methods of providing benefits under ... Part D ... for outpatient prescription drugs for which benefits are provided under Part B." The study is due by January 1, 2005.

The Part D prescription drug benefit was authorized in the MMA and will be effective January 1, 2006. For the first time in the history of the Medicare program, all beneficiaries will have access to subsidized prescription drug coverage. Up until now, Medicare has provided only limited outpatient prescription drug coverage under Medicare Part B. The new Part D prescription drug benefit will allow all Medicare beneficiaries to enroll in drug coverage through a prescription drug plan or a Medicare Advantage health plan with Medicare paying, on average, about 75 percent of the premium for basic coverage. Additional assistance will be provided to Medicare beneficiaries who have limited means. The MMA also provides options for employers and unions to maintain drug coverage for retirees. All the new Medicare benefits are voluntary.

Our initial examination of policy issues involved in moving coverage of separately billable Part B drugs to Part D suggests that such a change would not be desirable for most categories of Part B drugs, but may be worth considering for a limited number of categories. The majority of categories of Part B drugs are not good candidates for shifting to Part D because they are provided directly in a physician's office or provider setting, rather than being dispensed to a beneficiary by a pharmacy. There are, however, a few categories of Part B drugs that are more similar to drugs that will be covered under Part D. While policy arguments could be made for consolidating coverage of similar drug categories under one program, further analysis is necessary to fully understand the financial impacts of any such changes on beneficiaries and on the Federal budget. In the interim, the difference between Part B payment for drugs and typical market prices will be mitigated by the MMA change that will base most Part B drug payments on more accurate market-based prices rather than on the inflated average wholesale price (AWP).

Moreover, regardless of the potential merits of moving coverage of some categories of drugs from Part B to Part D, any additions to Part D coverage at this time would only add to the complex task facing potential drug plans sponsors in developing an initial bid and in administering the new Part D benefit. For this reason, we do not

recommend moving coverage of any drugs currently covered under Part B to Part D until we have at least two years of experience with the Part D program.

We intend to study further the issues involved with the consolidation of the various categories of drug coverage and to determine whether changes in coverage are warranted. We also intend to use our experience with the Medicare Replacement Drug Demonstration, which extends Medicare coverage to certain prescription medicines that can be self-administered and are substitutes for Part B drugs, to help inform our analysis of the issues related to consolidating categories of coverage. After we complete our further study, if we determine that a change for a category would be warranted, we will forward our proposals to Congress. In the interim, we intend to conduct substantial educational efforts to ensure that beneficiaries and potential drug plans sponsors understand the drug coverage available under both Medicare Part D and Medicare Part B.

Background

Part D provides broad coverage of drugs, biologicals, vaccines and insulin (and associated supplies). There are two exclusions from the definition of a Part D drug. First, certain drugs that are excludable or otherwise restricted by States under the Medicaid program are excluded from Part D. Second, drugs, biologicals and vaccines (henceforth referred to simply as drugs) available through Part A or Part B of Medicare are also excluded.

Specifically with regard to the latter category, any drug for which payment would be available under Parts A or B of Medicare, as prescribed and dispensed or administered to an individual, is excluded from Part D (even though a deductible may apply under Part B). Thus, some drugs can qualify for payment under Part B in some circumstances and under Part D in other circumstances, depending on the characteristics of the beneficiary or the way the drug is dispensed or administered. Dispensing or administration includes the setting, personnel, and method involved, and not simply the route of administration. In the Notice of Proposed Rulemaking for the Medicare Drug Benefit, we further proposed that payment for a drug under Part A or B is considered "available" to any individual who could sign up for Parts A or B, regardless of whether they actually enroll in those programs.

Drugs are covered under Part B in a variety of settings and under a variety of payment methodologies.

- Some drugs are paid on a cost basis or are part of a prospective payment, including: drugs packaged under the outpatient prospective payment system (OPPS); drugs furnished by End-Stage Renal Disease (ESRD) facilities and included in Medicare's ESRD composite rate; osteoporosis drugs provided by home health agencies under certain conditions; and drugs furnished by: critical

access hospitals' outpatient departments; rural health clinics; federally qualified health centers; community mental health centers; and ambulances.

- There are also 13 categories of drugs for which separate payment is made under Part B,[1] including: drugs furnished "incident to" a physicians' service; separately billable ESRD drugs; separately billable drugs provided in hospital outpatient departments; durable medical equipment (DME) supply drugs; other drugs covered as supplies; drugs used in immunosuppressive therapy; blood clotting factors; certain vaccines; antigens; parenteral nutrition; certain oral drugs used in cancer treatment; separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORFs); and intravenous immune globulin provided in the home.[2]

While all of these drugs are "provided under Part B," this report will focus only on those drugs for which separate payment is made, since there does not appear to be any obvious policy advantage to either breaking out drugs that are already part of a bundled payment or moving drugs that are part of a broader cost reimbursement payment to a provider.

Issues in Moving Drugs From Part B to Part D

There are at least nine considerations in making a determination about moving coverage from Part B to Part D. It should be noted that the same issues would be involved in considering moving a category of drugs from Part D to Part B.

- **Financial Impact on Beneficiaries** - The Part B benefit structure is significantly different from the benefit structure for defined standard coverage under Part D. Part B has a lower deductible, lower initial cost-sharing, and does not require 100 percent cost-sharing for a portion of spending. Part B does not, however, have catastrophic protection like Part D. Putting aside for the moment the low-income subsidy program under Part D, one can say that for <u>total</u> annual drug expenditures under roughly $22,000 (for 2006), Part B provides more generous drug coverage and for total expenditures greater than $22,000, Part D provides superior coverage.

  To actually determine how moving a category of drugs from Part B to Part D would affect beneficiaries' out-of-pocket costs, one would have to examine not only expenditures for the particular Part B drugs in question but also expenditures for

[1] If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay (with the exception of clotting factor), they are bundled into the Medicare Part A payment to the facility. However, if the beneficiary does not have Part A coverage or if Part A coverage for the stay has run out, hospitals are paid for Part B covered drugs based on Part B payment rules and SNFs are paid for Part B covered drugs based on cost.

[2] Medicare does make separate payment for blood and blood products and these products are regulated as biologicals by FDA. However, given that these products and their use is so far a field from the experience under a prescription drug benefit, the policy value of moving coverage to Part D is highly questionable. As a result, it is not discussed in this report.

existing Part D drugs that would typically be taken by such a person. For example, if a beneficiary had $5,100 in spending for existing Part D drugs (which would normally be associated with the level of out-of-pocket costs ($3,600) that would trigger the standard Part D catastrophic benefit's 5 percent cost-sharing), then moving a category of Part B drugs to Part D would lower the beneficiary's out-of-pocket costs. On the other hand, if the beneficiary had $2,250 in total drug spending for existing Part D drugs (which means the beneficiary would face 100 percent cost-sharing for any additional Part D spending until the catastrophic threshold was reached), then moving a category of Part B drugs to Part D would increase beneficiary cost sharing, provided the drug was not extremely expensive.

This analysis is made more complicated by the low-income subsidy provisions. For low-income subsidy eligible individuals, other than full dual eligibles or Qualified Medicare Beneficiaries (QMBs), the Part D benefit combined with cost-sharing subsidies looks much better than Part B. Both the deductible (if any) and cost-sharing would be lower than that under Part B. For full dual eligibles and for QMBs, however, Medicaid is currently paying the Part B cost-sharing,[3] with States having the option of charging nominal copays. Thus, moving Part B coverage to Part D would result in either individuals paying nominal amounts for the first time or in trading Medicaid nominal copays for the Part D low-income copays ($1 for generic drugs and $3 for name-brand drugs or $2 for generic drugs and $5 for name-brand drugs, depending on low-income category, for the non-institutionalized).

- **Budgetary Impact –** To the extent that moving a particular category of drugs from Part B to Part D would reduce cost-sharing for beneficiaries, it would likely increase overall Medicare program spending by increasing spending on Part D by more than the offsetting decrease in spending on Part B. An additional budget consideration is the difference in the level of payment provided for a drug under Part B compared to the average payment under Part D plans. While significant differences would have existed if Part B payment had continued to be tied to the inflated AWP, it is anticipated that for most drug payments the differences between payment under Part B and typical market prices will be mitigated by the MMA change to more accurate market-based prices.

- **Impact on Potential Plan Sponsors** – Moving a category of Part B drugs to Part D will not be viewed as positive by prescription drug plans (PDPs), since it would only add to the complex task that they face in developing an initial bid and in administering the new Part D benefit. This would particularly be the case for Part B drugs that are very expensive and used by a small subset of the population. Shifting coverage is less of an issue for Medicare Advantage plans, since they will provide comprehensive Medicare benefits (including Part A, Part B, and Part D services); however, such changes would have an impact on how costs are accounted for within the bidding system.

[3] The Medicaid program does not pay the full Medicare cost-sharing amount in situations where the Medicare payment is already greater than what the state would have paid if it were primary. In these situations, the state would just pay up to the Medicaid amount. Regardless, the beneficiary has no liability.

- **Competitively Determined Pricing** – Moving coverage of a category of drugs from Part B to Part D would mean that that these drugs would no longer be reimbursed on the basis of Medicare's administered prices but on rates negotiated between drug plans sponsors and drug manufacturers or health care providers. Increasing the universe of Medicare-covered drugs paid for on the basis of market mechanisms is clearly in keeping with a major policy thrust of the MMA. Within the Part B program, the MMA did create new competitive mechanisms that will be implemented in future years to determine Medicare payment for certain Part B drugs (for example, as an alternative to ASP-based payment at physician option) and for DME infusion drugs.

- **PDP Sponsor Experience –** The various categories of drugs covered under Medicare Part B are dispensed or administered in a wide range of settings (e.g. physicians' offices, hospital outpatient departments, ESRD facilities, pharmacies, beneficiaries' homes). Most categories of Part B drugs dispensed by entities other than pharmacies are typically included in commercial insurers' medical benefits, rather than their drug benefits. Consequently, pharmacy benefit managers (PBMs) and other entities that administer drug benefits for insurers may not have relationships with these providers or experience with the particular circumstances unique to the provision of these drugs. Moving drugs provided in these settings to Part D would require PDPs to develop relationships with these providers and implement new practices, increasing administrative complexity and costs.

- **Administrative Issues** – Moving drugs from Part B to Part D may ameliorate or exacerbate administrative complexity depending on the situation.

  --As indicated above, some drugs are covered under Part B under certain circumstances and under Part D under other circumstances (e.g., immunosuppressive therapy, parenteral nutrients, oral anti-emetics). This fact will create administrative problems for pharmacies and for other providers that bill for these drugs, as well as for Part B contractors and PDPs who process the claims. Ensuring that Medicare contractors and PDPs process claims correctly will be a formidable task since the information necessary to process the claim correctly may not be included on the electronic claim. From this perspective, program administration would be simpler for all involved if coverage for a specific form of a drug dispensed in a particular setting were under one program.

  --For those categories of Part B drugs not dispensed by pharmacies (e.g. drugs administered in physician offices, ESRD facilities, hospital outpatient departments), entities currently bill the Medicare claims processor. If these drugs were moved from Part B to Part D, entities would likely confront increased complexity as the number of contractors that they have to bill for their Medicare patients would increase from just the Medicare claims processor to that Medicare contractor and multiple PDPs.

--Some Part B drugs are dispensed directly to beneficiaries by pharmacies. Since pharmacies will already have relationships with PDPs for Part D drugs, it could simplify administration for pharmacies if these drugs were moved to Part D. In addition, some in the pharmacy industry have asserted that Medicare Part B imposes more administrative costs on pharmacies than other insurers because Medicare Part B does not currently have real-time claims adjudication. Thus, moving these drugs to Part D would reduce administrative burden.

- **Potential for Quality Improvement** - Drug plan sponsors will have systems in place to prevent drug–drug interactions. Moving Part B coverage to Part D would ensure that all of the drugs being taken by a beneficiary would be known to the PDP sponsor. Shifting Part B drugs to Part D could also improve the effectiveness of medication therapy management programs. For example, if inhalation drugs used with nebulizers were moved to Part D, or metered-dose inhalers were available under Part B, coverage of both forms of these inhalation drugs would be under one entity; thus, enhancing the potential for medication therapy management.

- **Eliminating Undesirable Incentives** – As currently structured, some drugs covered under Medicare Part B will have competitor drugs that are covered under Part D. Given differences in the cost-sharing structure for Part B and Part D, the question arises as to whether this will lead to medical decisions based on cost-sharing considerations. While implementation of Medicare Part D will actually lessen existing cost-sharing disparities across competitor drugs (as drugs that are not currently covered by Medicare will gain coverage under Medicare Part D), the differences in cost-sharing will not be eliminated entirely. In addition, providers would experience differences in their payment between Part B and Part D and potentially higher administrative costs under one program versus another. Again, it is possible that these differences could impact what should be medical decisions.

- **Impact on Part D Plan Premiums –** Moving drugs from Medicare Part B to Medicare Part D would increase Part D costs, and consequently, increase the average Part D beneficiary premium. While there would be an offsetting decrease in the Part B premium, it is possible that an increase in the Part D premium might affect beneficiaries' Part D enrollment decisions. In addition, to the extent that any of the drugs moved from Part B to Part D are particularly high costs drugs and a particular PDP experiences disproportionate enrollment of beneficiaries who use these drugs, the Part D premium would be higher for all beneficiaries enrolled in that plan.

Categories of Part B Drugs

As discussed earlier, there are 13 categories of Part B drugs that are separately billable. Below are descriptions of each category including a discussion of some of the key issues specific to each category that would need to be considered in determining whether these drugs should be transitioned from Part B to Part D.

- **Drugs Furnished "Incident To" a Physician's Service** - These are injectable or intravenous drugs that are administered predominantly by a physician or under a physician's direct supervision under the "incident to" a physician's service benefit. The statute limits coverage to drugs that are not usually self-administered. This determination is made on the basis of the drug rather than the beneficiary. If a drug is not self-administered by more than 50 percent of Medicare beneficiaries, it is considered "not usually self-administered". Under the "incident-to" provision, the physician must incur a cost for the drug, and must bill for it; examples of these drugs include: injectable prostate cancer drugs (lupron acetate for depot suspension, goserelin acetate implant); injectable drugs used in connection with treatment of cancer (epoetin alpha and darbepoetin alfa); intravenous drugs used to treat cancer (paclitaxel and docetaxel used to treat breast cancer); injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy; infliximab used to treat rheumatoid arthritis; and rituximab used to treat non-Hodgkin's lymphoma. Total Medicare carrier charges for all "incident to" drugs amounted to nearly $8 billion in 2003.

  The MMA mandated changes in payments for these drugs, which previously had been paid at 95 percent of the AWP. Beginning in 2004, payments were generally reduced to 85 percent of a fixed AWP, with some exceptions. Beginning in 2005, reimbursement will generally be based on 106 percent of the ASP. In 2004 and 2005, substantial modifications were made under the physician fee schedule to significantly increase payment for drug administration.

  Beginning in 2006, a competitive acquisition program will be phased in. Under that program, physicians can choose to no longer bill for drugs included in the program and instead receive them through competitively selected contractors that would bill Medicare. Alternatively, they can choose to continue acquiring the drugs in the marketplace and receiving Medicare reimbursement at the otherwise applicable payment amount.

  Moving these drugs from Part B would increase both financial risk and administrative complexity for PDPs. While a few insurers have pilot programs to provide certain injectable drugs to physicians via specialty pharmacies, insurers tend to include physician administered drugs as part of their medical benefits, rather than their drug benefits. Consequently, PBMs and other entities that administer drug benefits for insurers generally do not have experience with these types of drugs nor do they typically have the relationships with physicians required to successfully provide all "incident to" drugs. In addition, movement of these drugs to Part D raises administrative issues for physicians since it would require that they deal with both the Part B carrier and the PDP in order to be paid for services provided within one visit. To the extent that a physician has patients who are members of multiple PDPs, administrative complexity for the physician would be further increased. In addition, depending on how the PDPs would choose to structure Part D coverage for these drugs, it could also entail changes in how physicians obtain their drugs.

- **Separately Billable ESRD Drugs (including EPO)** - Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs is for erythropoietin (EPO), which is covered for dialysis beneficiaries when it is furnished by independent and hospital-based ESRD facilities, as well as when it is furnished by physicians. EPO furnished to ESRD beneficiaries by independent and hospital-based ESRD facilities is separately billed by such facilities and was paid at $10 per thousand units through 2004. In 2005, EPO will be paid based on acquisition costs for the year 2003 as determined by the Office of the Inspector General, increased to 2005 based on the producer price index. However, if a physician furnishes EPO to an ESRD beneficiary in the physician's office, then according to section 1881(b)(11)(B)(i) payment follows the same methodology as applies to other "incident to" drugs. In the most recent year for which data is available, Medicare paid $1.4 billion (2002) to facilities and $95 million (2003) to physicians for EPO for beneficiaries with ESRD.

  Other separately billable drugs include vitamin D analog injections (e.g. calcitriol) to treat bone deterioration and iron dextran (iron supplement needed for EPO to be effective). These drugs had been paid on the basis of 95 percent of AWP when furnished by an independent facility and on a cost basis when provided by a hospital based facility. In 2002, Medicare paid facilities approximately $700 million for the top 10 drugs in this category.

  In 2005, the payment rate to independent facilities for the other high volume separately billable ESRD drugs (i.e. the top nine drugs after EPO) will also be based on OIG determined acquisition costs updated to 2005. The remaining ESRD drugs billed by independent facilities will be paid at 106 percent of ASP for 2005. Separately billable ESRD drugs, other than EPO, furnished by hospital-based facilities continue to be paid reasonable cost in 2005. In addition, the MMA stipulated that HHS submit a report to Congress by October 2005 on a bundled prospective payment system for ESRD services. The statute also requires implementation of a 3-year demonstration program beginning in 2006 to test a bundled case-mix adjusted payment for ESRD services that would include drugs that are currently separately billable. Given the Congressionally mandated research and demonstrations planned to test bundled payment methods, it would be inconsistent to move these drugs from Part B to Part D.

- **Separately Billable OPD Drugs** – In 2005, while drugs costing less than $50 are incorporated into the prospective payment for the procedure in which they are provided, higher cost drugs will be billed separately and paid according to varying methodologies depending on which grouping the drugs fall under. For example, pass-through drugs will be paid at 106 percent of ASP*;* prior to 2005, these drugs were paid based on a percentage of AWP. Total OPD PPS payments for separately billed drugs amounted to $1.5 billion in 2003.

  Moving these drugs to Part D would create a number of problems. It would require hospitals to seek reimbursement from both its intermediary and the beneficiary's PDP

for services provided in a single encounter. Today, while these drugs are separately billable, they are still included on the claim form with the other services provided in the encounter. In addition, while CMS is currently required to make separate payment for these higher cost drugs until 2007, moving these drugs to Part D would eliminate the option of bundling some or all of these drugs in the future.

- **Durable Medical Equipment (DME) Supply Drugs** - These are drugs that require administration by the use of a piece of DME (e.g., a nebulizer, external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, which are administered through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). Medicare allowed charges paid through DME regional carriers (DMERC) for these drugs were nearly $1.3 billion in 2003. The other category of drugs Medicare covers as a DME supply are drugs for which administration with an infusion pump in the home is medically necessary (e.g. insulin, some chemotherapeutic agents). Medicare Part B charges paid by DMERCs for these drugs were about $96 million in 2003.

  Medicare reimbursement rates for inhalation drugs will be 106 percent of ASP beginning in 2005. Medicare is also authorized to provide a dispensing fee for inhalations drugs. For 2005, the final rule establishes a $57 monthly fee and a fee of $80 for a 90-day period. With respect to infusion drugs, beginning in 2004 the Medicare payment rate for infusion drugs is 95 percent of the October 1, 2003 AWP. Beginning in 2007, Medicare will phase in a competitive acquisition program for durable medical equipment and supplies, including infusion drugs but excluding inhalation drugs.

  With regard to inhalation drugs it is general medical practice that the first course of treatment is typically the use of metered-dose inhaler. These inhalers are not covered under Part B but will be covered under Part D. Thus, a case could be made for moving nebulizer drugs to Part D or for covering metered-dose inhalers under Part B to facilitate step therapy and coordination of care.

  While Medicare Part B covers infusible drugs that require a pump, the Part D program will be covering infusible drugs that do not require a pump. Similarly, Part B currently covers insulin used in conjunction with a pump, but Part D will cover insulin when injected. Will this coverage under both programs lead to situations where choice of drug or method of administration will be made based on the reimbursement under the programs or on whether a beneficiary is in that portion of Part D coverage that requires 100 percent cost-sharing? While a case can be made for moving these drugs to Part D, a case can also be made for covering all infusible drugs and all insulin under Part B. One final consideration is the competitive acquisition program for DME suppliers mandated by the MMA that is to be phased in beginning in 2007. Part B infusion drugs are contemplated to be within the scope of this

program. Thus, movement of Part B infusible drugs to Part D would appear to be inconsistent with MMA policy with regard to competitive acquisition.

- **Other Drugs Covered as Supplies -** Some drugs are covered as supplies that are an integral part of a diagnostic or therapeutic service; including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. The methods Medicare uses to reimburse providers for these drugs varies. Radiopharmaceuticals are paid by carriers according to local determinations, based on invoices. Low osmolar contrast media will be paid based on 106 percent of ASP in 2005. In 2003, total Medicare charges paid by carriers were $341 million for radiopharmaceuticals and $33 million for low osmolar contrast material. Given that these drugs are delivered as part of a procedure, they would not seem to be candidates for moving from Part B to Part D.

- **Drugs Used in Immunosuppressive Therapy** - These are mostly oral drugs used by Medicare beneficiaries who have received a Medicare-covered transplant (e.g., heart, kidney). In situations where a beneficiary receives a transplant prior to enrolling in Medicare, immunosuppressive drugs are not covered by Part B but will be covered under Part D. Medicare Part B charges paid by carriers for immunosuppressive drugs were about $289 million in 2003. Beginning in 2005, these drugs will be paid at 106 percent of ASP. The statute also provides for a supplying fee, which will be $50 per prescription for beneficiaries in the first month after a transplant and $24 per prescription for all other beneficiaries.

  Unlike "incident to" drugs, most immunosuppressive drugs are dispensed by pharmacies directly to beneficiaries. Thus, pharmacies would be dealing with a Medicare DMERC for claims for Medicare beneficiaries with Medicare covered transplants and with PDPs for all other beneficiaries using these drugs. Currently, some in the pharmacy industry have reported experiencing difficulties determining for a specific patient whether immunosuppressives are covered under Medicare or under another insurer. Having all Medicare coverage for oral immunosuppressive drugs for Medicare beneficiaries under Part D or Part B would prevent such confusion from arising. However, since commercial insurers typically include these drugs within their drug benefit, providing them under Part D would mimic current industry practice.

  The effect on beneficiary cost-sharing of providing coverage for all of these oral drugs under either Part D or Part B is uncertain and would require micro-level analysis. Whether beneficiary out-of-pocket costs would be increased or decreased as a result of such a change would depend on whether, and to what extent, the beneficiary's combined spending on Part D drugs triggers the Part D catastrophic benefit.

- **Blood Clotting Factors** - These are biologicals that promote blood coagulation to treat excessive bleeding and are used primarily by hemophiliacs competent to use such factors without medical supervision. Clotting factor is extremely expensive – 20

percent of beneficiaries using clotting factor submitted monthly claims in 2003 and had total allowed charges for the year that averaged close to $400,000. Medicare Part B charges paid by carriers for clotting factor were about $165 million in 2003. The Medicare Part B payment rate for clotting factor will be 106 percent of ASP plus a furnishing fee of $0.14 per unit for 2005. Separate payment for these factors is not limited to Part B. Under Part A, clotting factors are paid for as an add-on to the inpatient DRG payment for Medicare beneficiaries with hemophilia. This inpatient hospital add-on payment is equal to 95 percent of the AWP.

Given the availability of catastrophic protection under Part D, it is clear that a beneficiary needing clotting factor, who did not have Medigap or Medicaid coverage, would be better off if coverage were moved to Part D. However, moving these drugs to Part D could be problematic for PDPs, since they would be at financial risk for the cost of these very expensive drugs used by a small subset of beneficiaries. Since these factors are generally covered under commercial health insurance plans' medical benefits rather than drug benefits, private PBMs would not have experience with this product.

- **Certain Vaccines** - Currently the statute covers influenza and pneumococcal vaccines for all beneficiaries and hepatitis B for beneficiaries at high or intermediate risk. Part B deductible and coinsurance applies for hepatitis B vaccines but is waived for influenza or pneumococcal vaccines. Total Medicare charges billed to the Part B carriers for these drugs were $118 million for influenza, $26 million for pneumococcal, and $2 million for hepatitis vaccinations.[4] The Medicare reimbursement rate for vaccines is 95 percent of AWP.

  Since Part D drugs include vaccines, any new vaccines or existing vaccines not listed above would be covered under Part D (e.g. tetanus). Since vaccines are normally provided in the context of a physician's service, coverage under both programs raises administrative complexity issues for physicians and PDPs. Thus, an argument could be made for moving coverage of all vaccines to Part B.

- **Antigens** - Antigens are not covered under the "incident to" benefit, but rather are explicitly covered in the statute. They are prepared by a physician (usually an allergist) for a specific patient. The physician or physician's nurse generally administers them in the physician's office. In some cases, the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home. Medicare's payment is based on 106 percent of ASP. In 2003, the Medicare program had $135 million in total carrier allowed charges for antigens. While not an "incident to" drug, movement of antigens to Part D would raise similar issues to those discussed above under the "incident to" category. Antigens are generally treated as a medical benefit in private insurance.

[4] Carrier charges for hepatitis vaccinations are low because most Medicare charges for hepatitis vaccinations are billed to fiscal intermediaries by ESRD facilities.

- **Parenteral Nutrition** – Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. Parenteral nutrition is administered intravenously and is regulated as a drug by the FDA. It is relatively expensive on a per unit basis, though comparatively few patients meet Medicare's coverage criteria. Parenteral nutrients and associated equipment and supplies are paid on a reasonable charge basis. Medicare reasonable charges were frozen, by statute, from 1996 through 2002. Medicare charges were $115 million for parenteral nutrients in 2003. In addition, Medicare paid $12 million for parenteral supplies.

  Parenteral nutrients are covered under Part B when a beneficiary's intestinal tract is non-functioning but will be covered under Part D for other medical reasons. From a coverage perspective, it may be simpler to have parental nutrients covered entirely under Part B or Part D. It is the general practice in private insurance for parenteral nutrition to be handled as a medical benefit.

- **Certain Oral Drugs Used in Cancer Treatment** - This category includes oral chemotherapy drugs with an active ingredient that is also available in an intravenous form that is covered by Medicare Part B. Currently, there are only a small number of drugs on the market that meet this criterion. Under this category, Part B also provides coverage of oral anti-emetic drugs that act as a full replacement for an intravenous substitute. In 2003, Medicare carrier allowed charges were about $55 million for oral anti-cancer drugs and $2 million for oral anti-emetics. As of 2005, Medicare will reimburse these drugs at 106 percent of ASP. The statute provides for a supplying fee, which will be $24 per prescription for 2005.

  The fact that some anti-cancer and anti-emetic agents will be covered under Part B and others will be covered under Part D raises questions about whether prescribing decisions will be affected by payment incentives and cost-sharing impacts. Moving coverage of all oral anti-cancer and anti-emetic drugs to Part D would reduce the potential incentive effects, although not eliminate them entirely (because anti-cancer and anti-emetic agents that are not "usually self-administered" and might be substitutes for oral drugs would likely remain covered under Part B). Since oral anti-cancer and oral anti-emetic drugs are dispensed by pharmacies, moving coverage to Part D should simplify coverage determinations and reduce administrative complexity due to on-line claims adjudication. This may particularly be the case for oral anti-emetics, which are covered under Part B when prescribed in connection with cancer care and which will be covered under Part D when prescribed for other purposes. It is current industry practice where oral anti-emetics and oral anti-cancer drugs are dispensed by pharmacies to include coverage in the drug benefit.

- **Separately Billable CORF Drugs** – Beneficiaries who are outpatients of comprehensive outpatient rehabilitation facilities can receive drugs that are not usually self-administered as part of the CORF benefit. Total charges for these drugs were approximately $0.2 million in 2003. In 2005, CORFs will be paid at 106 percent of ASP for these drugs.

Moving these drugs to Part D would create similar issues to those discussed above with regard to separately billable OPD drugs. It would require a CORF to seek reimbursement from both its intermediary and the beneficiary's PDP for services provided in a single encounter. Today, while these drugs are separately billable, they are still included on the claim form with the other services provided in the encounter. In addition, it would eliminate the option of bundling these drugs in the future as part of a modified payment system for CORF services.

- **Intravenous Immune Globulin Provide in the Home** – The MMA created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. Coverage is provided if a physician determines that the administration of IVIG in the patient's home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product. In 2005, payment will be based on 106 percent of ASP.

  If coverage of IVIG in the home for beneficiaries with primary immune deficiency disease is left under Part B, IVIG home infusion providers would bill Part B in the case one diagnosis and Part D for all other indications. This could create some confusion but one would assume that diagnosis information would be readily available to the infusion provider. Whether beneficiaries would be better off with Part D rather than Part B coverage would depend on the cost of all the other drugs that beneficiaries with this diagnosis typically take. To the extent that beneficiaries would be better off financially, Medicare program payments would likely increase.

Recommendation

This brief review of the categories of Part B covered drugs should make clear that moving coverage involves a set of highly complex issues. The majority of categories of Part B drugs are not good candidates for shifting to Part D because they are provided directly in a physician's office or provider setting rather than being dispensed to a beneficiary by a pharmacy. There are, however, a few categories of Part B drugs that are more similar to covered Part D drugs. While a policy case could be made for consolidating coverage of these similar drug categories under one program, further analysis is necessary. Given that the movement of any drugs from Part B to Part D would only add to the complex task facing potential drug plans sponsors in developing an initial bid and in administering the new Part D benefit, we do not recommend that such changes be considered until we have at least two years of experience with the Part D program.

We intend to study further the issues involved with the relationship between Part B and Part D drug coverage with an eye toward reexamining the status of these drugs a few years into implementation of the Part D program, including assessments of the impact of such a change on beneficiaries, drug plan sponsors and the Federal budget. At that time, to the extent that changes with regard to coverage are warranted, we will

forward our proposals to the Congress. In the meantime, we intend to conduct substantial educational efforts to ensure that beneficiaries and potential drug plans sponsors understand the drug coverage available under both Medicare Part D and Medicare Part B.

Appendix - Separately Billable Part B Drugs

Categories	2005 Payment Method	2003 Total Charges ($'s in millions)
Drugs Furnished "Incident To" a Physician Service	ASP+6%	$7,972 *
Separately Billable ESRD Drugs		
- EPO for ESRD	For facilities - 2003 estimated acquisition costs updated to 2005 For physicians - ASP+6%	$1,400 to facilities ** $95 to physicians
- Other Drugs	For hospital-based facilities – reasonable costs For independent facilities - 2003 estimated acquisition costs updated to 2005 or ASP+6% (based on the drug)	$700 for top 10 drugs
Separately Billable OPD Drugs	Methodology varies based on category	$1,470
DME Supply Drugs		
- Inhalation drugs	ASP+6%	$1,295
- Infusion drugs	95% of 10/1/03 AWP	$96 ***
Other Drugs Covered as Supplies		
- Radiopharmaceuticals	Local (invoice)	$341 ****
- Low Osmolar Contrast Media	ASP+6%	$33 ****
Drugs Used in Immunosuppressive Therapy	ASP+6%	$289 ****
Blood Clotting Factors	ASP+6%	$165****
Certain Vaccines		
- Influenza	95%AWP	$118
- Pneumococcal	95%AWP	$26
- Hepatitis B	95%AWP	$2 ****
Antigens	ASP+6%	$135****
Parenteral Nutrition		
- Nutrients	Reasonable charges	$115
- Equipment and Supplies	Reasonable charges	$12
Certain Oral Drugs Used in Cancer Treatment		
- Anti-cancer Agents	ASP+6%	$55 ****
- Anti-emetics	ASP+6%	$2 ****
Separately Billable CORF Drugs	ASP+6%	$0.2
Intravenous Immune Globulin Provide in the Home	ASP+6%	NA

* Includes non-ESRD EPO and infusion drugs paid by local carriers

** 2002 Charges

*** Benefits paid by DME Regional Carriers only -- payments by local carriers shown as part of "incident to" total

**** Benefits paid by carriers only, payments are also made by intermediaries