DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

September 12, 2006

Memorandum To: All Part D plans

Subject: Medicare Part D Manual – Draft of Chapter 6

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Today we are releasing for comment the draft of Chapter 6 of the Medicare Part D Manual. The draft of Chapter 6 consolidates previous guidance, questions and answers, and HPMS memos. In particular, the revised draft contains information specific to the following areas:

- Definition of a Part D Drug
- Part D Exclusion
- Formulary Requirements
- Transition.

Comments on the draft of Chapter 6 must be received by CMS no later than 5:00 p.m. EST, Tuesday, September 26, 2006. Comments must be submitted via e-mail at PartDBenefitImpl@cms.hhs.gov. Please include ***Chapter 6*** in the subject line of the email. If you have questions contact Greg Dill (312) 353-1754.

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Medicare Part D Manual

Chapter 6 – Part D Drugs and Formulary Requirements

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Note: This manual is subject to change to both periodic and annual updates and currently reflects CY 2007 guidance.

10 Definition of a Part D Drug

Part D drugs are defined in Title XVIII of the Social Security Act (the Act) and in the regulations (42 CFR 423.100).

10.1 General

Subject to the exclusions specified in section 20 of this chapter, a Part D drug means a drug that may be dispensed only upon a prescription, is being used for a medically accepted indication as defined by section 1927(k)(6) of the Act, and is either:

- A drug that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
- A biological product described in section 1927(k)(2)(B)(i) through (iii) of the Act;
- Insulin described in section 1927(k)(2)(C) of the Act;
- Medical supplies associated with the injection of insulin;
- A vaccine licensed under section 351 of the Public Health Service Act.

10.2 Covered Part D drug

A covered Part D drug is a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a covered determination or appeal under 423.566, 423.580, and 423,600, 423.610, 423.620 and

423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with 423.124.

10.3 Commercially Available Combination Products

Commercially available combination prescription drug products that contain at least one Part D drug component are Part D drugs when used for a "medically accepted" indication, unless CMS makes the determination that such product, as a whole, belongs in one of the categories of drugs excluded from coverage under Part D. If CMS has not provided guidance to exclude a specific combination product, such combination product, so long as it contains at least one Part D drug component, should be considered a Part D drug unless it is excluded from coverage under Part D for another reason.

10.4 Extemporaneous Compounds

Compounded prescription drug products can contain (1) all Part D drug product components; (2) some Part D drug product components; or (3) no Part D drug product components. Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug.

The labor costs associated with mixing a compounded product that contains at least one Part D drug component can be included in the dispensing fee (as defined in 423.100).

10.5 Medical Supplies associated with the Injection of Insulin

Medical supplies associated with the injection of insulin include syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes. However, test strips, lancets and needle disposal systems are not considered medical supplies associated with the injection of insulin for purposes of Part D.

10.6 Medically Accepted Indication

Section 1860D-2(e)(1)(B) limits "medically accepted indication," by reference to section 1927 (k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection 1927(g)(1)(B)(i). The compendia are:

(I) American Hospital Formulary Service Drug Information;
(II) United States Pharmacopeia-Drug Information; and
(III) DRUGDEX Information System.

Part D plans are responsible for ensuring that covered Part D drugs are prescribed for "medically accepted indications". Plans may rely on utilization management policies and procedures to make such determinations but pharmacists are not required to contact each

prescriber to verify whether a prescription is being used for other than a medically accepted indication.

"Medically accepted indication" refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Plans may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

10.7 Drug Purchased in another Country

Plans must exclude Part D drugs from qualified prescription drug coverage if they are not used and sold in the United States. In addition, Part D plans may only pay for drugs that satisfy the definition of Part D drug. In general, such definition requires FDA approval for sale in the United States. Therefore, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved.

10.8 Drugs used to Treat Opioid Dependence

Prescription Drug Plans and MA-PDs must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex®, but must include combination products when medically necessary (e.g. Suboxone®). For any new enrollee, CMS requires plans to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS' non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

Prescription Drug Plans cannot include coverage for drugs that do not satisfy the definition of Part D drug. A Part D drug is defined, in part, as "a drug that may be dispensed only upon a prescription." Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (Note: Methadone is a Part D drug when indicated for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.

10.9 DESI Drugs

For a drug to be available for reimbursement by a Part D Sponsor it must meet the definition of a Part D drug. Section 1860D–2(e)(1) of the Social Security Act (the Act) generally defines a Part D drug to include those drugs ''that may be dispensed'' only upon a prescription and that meet the requirements of section 1927(k)(2) of the Act. Section 1927(k)(2) generally requires that the drug be approved by the FDA or is otherwise described under sections 1927(k)(2)(A)(ii) and (A)(iii) of the Act. Sections

1927(k)(2)(A)(ii) and (A)(iii) address those drugs affected by the Drug Amendments of 1962 (amending of the FD&C Act), which require that a new drug be proven effective, as well as safe. FDA's Drug Efficacy Study Implementation (DESI) evaluates the effectiveness of those drugs that had been previously approved on safety grounds alone. These drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is only permitted if an NDA is approved for such drugs. The vast majority of the DESI proceedings have been concluded, but a few are still pending.

Only those agents that have not yet completed review under the DESI program, or those drugs that were not found to be "less than effective" (LTE) under the DESI program, may be included in the Part D benefit. A full description of FDA's policy and DESI process can be found at: http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg440-100.html . As with all drug products on the US market, the manufacturer bears the responsibility of ensuring its products are safe and effective and approved in accordance with FDA regulations prior to marketing.

As FDA continues to undertake reviews under the DESI program and announces results of it hearings, we would expect Part D Sponsors to adjust their formularies accordingly, as they should with any other FDA drug product announcement.

The definition of a Part D drug does not include LTE DESI drugs or those identical, related or similar (IRS) drugs to the LTE DESI drug. Such drugs are identified by having a DESI indicator code of either 5 or 6. A list of LTE DESI drugs with indicator codes of 5 or 6 can be found on the CMS website at www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/desi.pdf.

10.10 Over-the-counter products (OTCs)

The definition of a Part D drug does not include OTCs. Therefore, Part D plans cannot include OTCs in their drug benefit or supplemental coverage. However, CMS will allow Part D plans the option to provide this alternative as part of their administrative costs structure, including limitation to approved step therapy protocols as part of a utilization management program. Please refer to upcoming Chapter 7 Section 60 of the Medicare Part D manual for further discussion of this option.

10.11 Common Home Infusion Drugs

CMS, in conjunction with industry partners, has identified a list of acute care drugs that are most commonly utilized in the home infusion setting. The use of these drugs or drug classes often results in an earlier hospital discharge and reduced healthcare costs. Rapid access to these agents is imperative for these health care transitions. It is CMS' expectation that Part D plan sponsors will not implement policies that could potentially delay or restrict beneficiary access to these important agents. In general, should prior authorization or other utilization management edits apply to any of these agents, we

would expect that plan sponsors handle these in an expedited manner in order to facilitate hospital discharge in appropriate time frames. In addition, for CY 2007, it is our expectation that Part D plan sponsors assure appropriate beneficiary access to these drugs or drug classes via formulary inclusion. See Appendix A for a list of commonly utilized home infusion drugs.

10.12 Multiple Source Drugs

A multi-source drug refers to the branded product when the same drug is also available generically. If a prescription may be filled with the generic version of a drug, the pharmacy may choose to dispense the generic or prefer to dispense a branded multi-source drug, depending upon which product the pharmacy purchases at a better price. Under this scenario, the beneficiary pays the lower copayment regardless of whether they received the generic or "preferred" branded multi-source drug. Alternatively, the plan may have identified a specific branded multi-source drug as a preferred product to be used whenever a generic could be dispensed and, therefore, the beneficiary would pay the lower cost sharing in this instance, as well. However, if the pharmacy is required to dispense a branded multi-source drug (for instance, if a physician requires dispense as written), and that drug is not identified by the plan as a preferred multi-source drug, the beneficiary would be required to pay the higher copayment.

20 Part D Exclusions

20.1 Excluded Categories

Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), except for smoking cessation agents.

Excluded:

- Agents when used for anorexia, weight loss, or weight gain.
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

[Effective as of January 1, 2007] In addition, ED drugs will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. However, ED drugs will not meet the definition of a Part D drug for other off-label uses not approved by the FDA. This includes non-FDA approved uses included in one of the compendia listed in section 1927(g)(1)(B)(i) of the Act : American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, and DRUGDEX Information System.

Not Excluded:

- Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes.
- Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.
- Vitamin D analogs such as calcitriol, doxercalciferol, paricalcitol and dihydrotachysterol, when used for a medically accepted indication as defined by section 1927(k)(6), are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3).
- Prescription-only smoking cessation products.
- Prescription Niacin Products (Niaspan, Niacor).

See Appendix B for further clarification of Part D coverage or non-coverage of specific products/drugs/drug categories.

20.2 Drugs Covered under Medicare Part A or B

Part D excludes any drug for which payment as so prescribed and dispensed or administered with respect to an individual would be available (or would be available but for the application of a deductible or an individual's choice not to enroll in Medicare Part A or Part B) under Medicare Part A or Part B for that individual. This clarification was primarily related to individuals who did not elect to enroll in Part B or whose enrollment in Part B was not effectuated until after their effective date of enrollment in Part D. However, the issue of applicability of Part D coverage has also arisen in the context of inpatients in acute care hospital settings (including long-term care hospitals, which are certified as acute care hospitals) who have exhausted their Part A inpatient stay benefit, but who require and continue to receive a level or care that qualifies them for a Part A inpatient stay.

See Appendix C for further explanation and clarification of specific issues regarding coverage under Medicare Part B.

20.2.1 Exhausted Part A Benefits

Drugs provided in an inpatient setting to an individual who has exhausted his or her lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Unlike a beneficiary who, for example, chooses not to buy into Part B, there is no way for an individual who has exhausted his or her Part A inpatient stay benefit to obtain coverage under Part A for his or her drugs; therefore, Part D coverage may be available to a Part D enrollee who has exhausted his or her Part A inpatient stay benefit and who remains in that inpatient setting (provided the drug would otherwise be covered under Part D). See Chapter 5 for a greater explanation of settings.

20.2.2 Plan Due Diligence in Prior Authorization of Part B versus Part D Coverage Determination

Plans may rely upon physician information included with the prescription, such as diagnosis information (e.g., to determine whether the prescription is related to a Medicare covered transplant) or location of administration (e.g., to determine if the prescription is being dispensed for a beneficiary in a nursing home) to the same extent they rely on similar information acquired through documentation from physicians on prior authorization forms. Assuming the indication on the script is sufficient to make the coverage determination, there is no need in such cases to require additional information to be obtained from the physician.

To the extent that the plan requires its contracted pharmacies to report the information provided on the prescription to assist in the determination of Part B versus Part D coverage, the plan may rely on the pharmacist's report of appropriate information to make the coverage determination under Part D. For example, for cases in which Prednisone is prescribed for a condition other than immunosuppression secondary to a Medicare-covered transplant, and this is indicated on the prescription, a plan may cover the drug under Part D without seeking further information from the prescribing physician.

This clarification should not be construed to indicate that a Part D plan may not impose prior authorization or other procedures to ensure appropriate coverage under the Medicare drug benefit. The Part D plan is ultimately responsible for making the initial Part D coverage determination. However, we believe that the plan will have met appropriate due diligence standards without further contacting a physician if necessary and sufficient information is provided on the prescription, and the contracted pharmacy is able to communicate this information to the plan in order to make the coverage determination.

20.3 Coverage under Enhanced Benefit

A Part D plan may include supplemental coverage of a drug that would meet the definition of a Part D drug but for the application of section 20.1 of this chapter.

20.4 Application of General Exclusion Provisions

In accordance with section 1860D-2(e)(3), a Part D plan may exclude from qualified prescription drug coverage any Part D drug:

- For which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines); or
- Which is not prescribed in accordance with the Part D plan.

Such exclusions are coverage determinations subject to reconsideration and appeal.

Unlike other Part D Drugs that may be excluded when not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Part D vaccines may only be excluded when their administration is not reasonable and necessary for the prevention of illness.

30 Formulary Requirements

A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet requirements for the following:

- Pharmacy and Therapeutics Committee
- Provision of an Adequate Formulary
- Transition Process
- Limitation on Changes in Therapeutic Classification
- Provision of Notice Regarding Formulary Changes
- Limitation of Formulary Changes Prior to Beginning of Contract Year
- Provider and Patient Education
- Formulary Changes during the Plan Year

30.1 Pharmacy and Therapeutics (P&T) Committee

A Part D sponsor's formulary must be developed and reviewed by a P&T Committee that meets specific requirements with respect to:

- Membership
- Conflict of Interest
- P&T Member Disclosure to CMS
- Meeting Administration
- Formulary Management
- Formulary Exceptions
- P&T Committee Role

30.1.1 Membership

- P&T committee members must come from various clinical specialties that adequately represent the needs of plans beneficiaries (i.e., include representation of "high volume specialists" in the standard terminology of the industry).
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both.
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D plan and pharmaceutical manufacturers. Such P&T committee members may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence. In addition, panel providers in a staff model HMO may be considered independent and free of conflict to the extent that any remuneration received from a Part D plan is limited to his or her clinical responsibilities for the care of plan enrollees.

30.1.2 Conflict of Interest

- P&T committee member should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

30.1.3 P&T Committee Member Disclosure to CMS

In the event the Part D Applicant/Sponsor has entered into a confidential agreement such that the PBM will not disclose its P&T Committee membership to the Part D Applicant/Sponsor, then it is the Part D Sponsor's responsibility to notify CMS that this information will be submitted by the Sponsor's PBM. Moreover, the Part D Applicant/Sponsor must ensure that the PBM notifies CMS of the P&T Committee membership. The Part D Applicant/Sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract and the Sponsor must ensure that the PBM notifies the Sponsor that this information has been successfully submitted to CMS.

30.1.4 Meeting Administration

- P&T committee should meet on a regular basis, and not less frequently than on a quarterly basis.
- P&T committee decisions regarding formulary development or revision must be documented in writing.

30.1.5 Formulary Management

- P&T committee must review for clinical appropriateness, the practices and policies for formulary management activities, such as prior authorizations, step

therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access. P&T committee recommendations regarding these activities are advisory only and not binding on the Part D plan.

- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy.
- The P&T committees will be required to establish and document procedures to assure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities (S42 CFR § 423.120(b)(1)(viii). P&T committee recommendations regarding which Part D drugs are placed on a plan's formulary are binding on the Part D plan.
- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies as well as other sources of appropriate information.
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers.
- The P&T committee will make a reasonable effort to review a new FDA approved drug product within 90 days and will make a decision on each new chemical entity within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved. We set this timeframe in response to public comment on our proposed guidance for 2006, but note that plans must make access to new drugs available to enrollees when medically appropriate via exceptions processes even before this deadline.
- P&T committee will evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.
- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.

30.1.6 Formulary Exceptions

P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. Part D coverage determinations and appeals information can be found in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

30.1.7 P&T Committee Role

At a minimum, a transition process will address procedures for medical review of non formulary drug requests and, when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. We will look to transition process submissions for assurances that a plan's pharmacy and therapeutics (P&T) committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests. P&T committee involvement will help ensure that transition decisions

appropriately address situations involving enrollees stabilized on drugs that are not on the plan's formulary (or that are on the formulary but require prior authorization or step therapy under a plan's utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.

30.2 Provision of an Adequate Formulary

We encourage plans to submit formularies similar to those in widespread use today. We will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, to satisfy the MMA requirement that a plan's categorization system does not substantially discourage enrollment to any group of beneficiaries. We also will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Plans may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

30.2.1 Formulary Categories and Classes

Part D Formularies must include drug categories and classes that cover all disease states. CMS will evaluate the sufficiency of a Part D plan's formulary categories and classes in conjunction with the formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.

Part D plans that utilize a classification system that is consistent with the USP classification system, available at www.usp.org, will satisfy a safe harbor and thus CMS will approve their formulary classification system. For plans that choose to adopt an alternative to USP's classification structure, CMS will check the plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, information available at www.ashp.org/ahfs.

Each category or class must include at least two drugs (unless only one drug is available for a particular category or class, or only 2 drugs are available but 1 drug is clinically superior to the other for a particular category or class), regardless of the classification system that is utilized. The two drug minimum requirement must be met through the provision of two chemically distinct drugs. In other words, Part D plans will not meet this requirement by including only two dosage forms or strengths of the same drug, or a brand-name drug and its generic equivalent. Although different strengths or dosage forms of the same drug do not count towards satisfying the two drug minimum requirement, CMS generally expects Part D plans to include multiple strengths and dosage forms, when available, for each drug included in each category or class.

CMS may require more than two drugs for particular categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary would substantially discourage enrollment in the plan by beneficiaries with certain disease states.

30.2.2 Formulary Benefit Management Tools

Prior Authorization, Step Therapy, and Quantity Limitations

CMS will look to existing best practices to check that plans' use of these utilization management tools is consistent with such practices. We will look to current industry standards as well as appropriate guidelines that might be found from expert organizations and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS will assure that plans' use of such tools is consistent with best practices. CMS will also compare formularies amongst the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Our expectation is that these techniques will be used in Part D formularies consistently with the way they are applied in existing formulary systems. In cases where a plan may fall outside of best practices, the plan will be asked to provide a reasonable justification for its practices.

All formularies will be evaluated using the criteria outlined in 30.2.7. Outliers for each area of review will be further evaluated by CMS to determine whether the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would cause discrimination. If any of the outliers appear to create problems of access, plans will have the opportunity to present reasonable clinical justifications.

30.2.3 Long-term Care Accessibility

Part D plans will be required to provide medically necessary prescription drug treatments for enrollees in the general Medicare population, as well as those enrollees who reside in long-term care (LTC) facilities. For example, it is CMS' expectation that plans provide coverage of dosage forms of drugs that are widely utilized in the LTC setting such as unit dose products, liquid, chewable, and parenteral preparations. Further, while nebulized solutions may not be required on all formularies, we would expect plans to also cover these dosage forms under circumstances in which Part B coverage does not exist. When determining days supplies for residents in LTC facilities, Part D plans should follow industry best practices and allow for at least 31 days per fill.

30.2.4 Specialty Tiers

Section 423.578(a)(7) of the Part D regulations allows Part D plans to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to ensure that a Part D plan does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.

- Cost-sharing associated with the specialty tier is limited to 25% in the initial coverage range (or actuarially equivalent for plans with decreased or no deductible basic alternative benefit designs).
- Only Part D drugs with plan negotiated prices that exceed $500 per month may be placed in the specialty tier.

If all drugs within a category or class meet the criteria for inclusion in the specialty tier, then a plan does not need to identify a preferred drug for that category or class.

30.2.5 Six Classes of Clinical Concern

Part D plan formularies must include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

Formularies must include substantially all drugs in these six categories that are available on April 17, 2006. New drugs or newly approved uses for drugs within the six classes that come onto the market after April 17, 2006 will be subject to an expedited Pharmacy and Therapeutic committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement.

"Substantially all" in this context means that all drugs and unique dosage forms in these categories are expected to be included in plan formularies, with the following exceptions:

- multi-source brands of the identical molecular structure
- extended release products when the immediate-release product is included
- products that have the same active ingredient or moiety
- dosage forms that do not provide a unique route of administration (e.g. tablets and capsules)

Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. If a plan cannot determine at the point of sale that an enrollee is not currently taking a drug (e.g. new enrollee filling a prescription for the first time), plans shall treat such enrollees as currently taking the drug. For beneficiaries who begin treatment with drugs in these categories other than HIV/AIDS drugs, plans may use these techniques to manage therapy. For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models (except that Fuzeon must be listed on formularies but may have prior authorization for new users). Plans may, of course, conduct consultations with physicians regarding treatment options and outcomes in all cases.

30.2.6 Submission of Multiple Formularies

CMS recognizes that plans may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. We have the responsibility to ensure that there are meaningful differences between multiple formulary submissions from one organization to reduce confusion amongst beneficiaries. CMS may request that plans withdraw a formulary in which no meaningful differences can be demonstrated.

30.2.7 Formulary Performance and Content Review

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The current formulary requirements are subject to change and/or revision.

CMS requires formulary drug lists to pass the following checks:

- CMS will review formularies for at least one drug in each of the Formulary Key Drug Types identified by USP. Best practice formularies commonly include at least one drug in each of the Formulary Key Drug Types as a minimum on their formulary. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP Formulary Key Drug Types. If a USP Formulary Key Drug Type only includes drugs that are primarily covered under Part B, it is not CMS' expectation that these Key Drug Types be represented on formularies. Similarly, if only over-the-counter (OTC) or statutorily excluded drugs, or drugs that were determined by the FDA to be less than effective (LTE), comprise a Key Drug Type, plans do not need to include representative drugs on the formulary. A list of Formulary Key Drug Types that are exempt from this drug list review check can be found in Appendix D.

- CMS will review tier placement to provide an assurance that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.

- CMS will analyze formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. Examples of these may include asthma,

diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process. Drugs or drug classes included within these widely accepted guidelines will not place undue burden on plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

- CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the general Medicare and the dually eligible population (Appendix E). This list is derived from the Medicare Current Beneficiary Survey (MCBS) data from 2002 and the Department of Health and Human Services Office of Inspector General (OIG) study: Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs. As with the MCBS data, the drugs identified by the OIG will be expanded to the class level, not the specific drug identified by the report. CMS understands that plans will not provide identical coverage of these drug classes, and our review will focus on assuring that plans present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow us to ensure that plans are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

30.3 Formulary Changes

30.3.1 Limitation on Changes in Therapeutic Classification

Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change formulary categories and classes other than at the beginning of each plan year.

30.3.2 Limitation of Formulary Changes Prior to Beginning of Contract Year

Except when the Food and Drug Administration deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period.

30.3.3 Midyear Formulary Changes

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the plan year. We believe that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the plan. However, prescription drug therapies are constantly evolving, and new drug availability, new medical knowledge, and new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year. As recognized in the statute and regulations, these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

30.3.3.1 Policy Regarding Formulary Changes

We have a 4 part policy regarding formulary changes:

- Part D plans may expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by lowering the tier of a drug, or deleting utilization management requirements any time during the year.
- Part D plans may not change their therapeutic categories and classes in a formulary other than at the beginning of each plan year, except to account for new therapeutic uses and newly approved Part D drugs.
- Formulary Maintenance Changes: After March 1, Part D plans may make maintenance changes to their formulary, such as replacing brand-name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness. Those changes must be made in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists and "affected enrollees."
- Other Formulary Changes: Part D plans may only remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and "affected enrollees." For these additional types of formulary changes approved by CMS for 2006, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts.

Note: CMS must approve any changes to a Part D Sponsors formulary; however, Part D plans are not required to obtain CMS approval or give 60 days notice when removing formulary drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

30.3.3.2 Formulary Maintenance Changes

In order to promote best practices and protect the interests of Medicare beneficiaries, CMS will generally give positive consideration to the following types of formulary changes:

- Removal or placement in less preferred tier of a brand drug upon the availability and addition of an A-rated generic or multi-source brand equivalent, at a lower tier or cost to the beneficiary.
- Removal of a non-Part D drug inadvertently included on the formulary.
- Removal of a drug based upon a new FDA "black box" warning or market withdrawal.
- Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g. CDC's recommendation against using older antivirals for treatment and prophylaxis of the flu).
- The addition of utilization management when necessary to effectuate other approved formulary changes (e.g. prior authorization on a brand drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

Part D plans will need to provide this type of justification when submitting these formulary change requests, but may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission. Part D plans are required to send 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and "affected enrollees" (except for FDA or manufacturer withdrawals).

30.3.3.3 Other Formulary Changes

Experience with formulary management indicates that the vast majority of formulary changes are "maintenance" changes that would generally be approved by CMS. CMS will review additional types of formulary change requests and their corresponding justification. Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts. These additional types of change requests include, but are not limited to:

- Changing preferred or non-preferred formulary drugs, adding utilization management, or increasing cost sharing on preferred drugs (unrelated to the reasons stated above);
- Removing dosage forms; or
- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

If CMS disapproves a formulary change request, the justification for disapproval will generally be based on one of the following:

- The reasonableness and/or necessity for the proposed change in the context of preventing any appearance of "bait and switch" in the formulary. Medicare beneficiaries select Part D plans, in part, based on the formulary that is marketed during annual open enrollment and, therefore, have a legitimate expectation that

they will have continuing access to coverage of the Part D drugs they are using throughout the plan year. This beneficiary expectation will be balanced against the plan's desire to practice good formulary management in order to provide a low-cost, high-quality prescription drug benefit that continues to effectively meet the needs of beneficiaries. Part D plans may avoid any appearance of a "bait and switch" concern by exempting enrollees who are currently using the affected drugs from the formulary change for the remainder of the plan year.

- The proposed change on its face in the context of substantially discouraging enrollment by certain beneficiary groups.
- The impact of the proposed change on the formulary as a whole to ensure the formulary continues to satisfy the minimum formulary requirements established by CMS.

Because these additional types of change requests will require more extensive review by CMS, Part D plans must not implement such changes until they receive explicit notification of approval from CMS and must not issue any beneficiary notices of such forthcoming changes prior to receiving explicit and affirmative CMS approval.

30.3.4 Provision of Notice Regarding Formulary Changes

Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in 423.454), entities providing other prescription drug coverage (as described in 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective.

In addition, a Part D plan must either:

- Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or
- At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change.

The written notice must contain the following information:

- The name of the affected covered Part D drug;
- Whether the plan is removing the covered Part D drug or changing its preferred or tiered cost-sharing status;
- The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;
- Alternative drugs in the same therapeutic category or class or cost-sharing tier and expect cost-sharing for those drugs; and
- The means by which enrollees may obtain a coverage determination under section 423.566 or exception under section 423.578.

As an alternative to providing written notice, Part D plans may provide such notice electronically if, and only if, an enrollee affirmatively elects to receive such notice electronically.

Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the advanced notice requirements specified in this section. However, Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in 423.454), entities providing other prescription drug coverage (as described in 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements set forth in this section.

30.3.5 Formulary Change Notice in Advance of Upcoming Contract Plan Year

Consistent with current guidance, enrollees must receive an annual notice of change (ANOC) by October 31st prior to the upcoming contract year. The ANOC is intended to outline benefit changes for the upcoming year including changes in cost-sharing and drug tier structures. Because the upcoming year's formulary is viewed as a new formulary, plans are not required to identify specific drug changes impacting enrollees in their explanation of benefits, or provide a 60-day notice of changes for the upcoming year's formulary. However, enrollees must receive a comprehensive or abridged formulary with the ANOC, which will provide enrollees with at least 60 days to review the new formulary to determine if their medications are covered and whether the cost-sharing for their covered medications will change for the 2007 contract year.

After enrollees receive their ANOC on October 31st of a given year, CMS expects plan sponsors to select one of the following two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary:

- Provide a transition process for current enrollees consistent with the transition process required for new enrollees beginning January 1, 2007. In order to prevent coverage gaps, plans choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated), consistent with the 2007 Formulary Transition Guidance, and provide enrollees with notice that they must either switch to a drug on the plan's formulary or get an exception to continue taking the requested drug; or

- Effectuate a transition for current enrollees prior to January 1, 2007. In effectuating this transition, plans must aggressively work to (1) prospectively transition current enrollees to a therapeutically equivalent formulary alternative; and (2) complete requests for formulary and tiering exceptions to the new formulary prior to January 1, 2007. If a plan sponsor approves such an exception request pursuant to the Part D regulations, the plan sponsor shall authorize payment prior to January 1, 2007 and provide coverage beginning January 1, 2007. If, however, plans have not successfully transitioned affected enrollees to a therapeutically equivalent formulary alternative or processed an exception request

by January 1, 2007, they will be expected to provide a transition supply beginning January 1, 2007 and until such time as they have effected a meaningful transition.

30.4 Transition

A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must satisfy requirements for the following:

- Transition Requirements
- General Transition Process
- Current Enrollee Transitions
- Emergency Supply for Current Enrollees
- Transition Process in the Retail Setting
- Transition Process in the LTC Setting
- Transition Extension

30.4.1 Transition Requirements

In creating standards for a transition process, we have attempted to balance safeguards for a smooth transition process for plan enrollees with maximum flexibility for plan sponsors in managing their prescription drug benefit offerings. A transition process is necessary with respect to: (1) the transition of new enrollees into prescription drug plans on January 1, 2007 following the 2006 annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage in 2007; (3) the transition of individuals who switch from one plan to another after January 1, 2007; and (4) enrollees residing in long-term care (LTC) facilities. Plans should also consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.

Transition process requirements will be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a plan's formulary, and (2) Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules, since a formulary drug whose access is restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee. See section 30.4.5.

30.4.1.1 P&T Committee Role

See section 30.1.7.

30.4.1.2 Temporary One-Time Transition Fills

A plan's transition process must address situations in which an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the plan's exception process to provide

access to Part D drugs that are not covered. This may be particularly true for full-benefit dual eligible beneficiaries who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Plans must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

A plan may charge cost-sharing for a temporary supply of drugs provided under its transition process. Cost-sharing for transition supplies for low-income subsidy (LIS) 2007 eligibles can never exceed the statutory maximum copayment amounts ($3.10 or $5.35 copays, or 15% coinsurance, depending on the level of LIS in 2007 for which a particular enrollee qualifies). For non-LIS enrollees, a plan must charge cost-sharing based on one of its approved drug cost-sharing tiers (if the plan has a tiered benefit design), and this cost-sharing must be consistent with cost-sharing that the plan would charge for non-formulary drugs approved under a coverage exception.

30.4.1.3 Transition Timeframes

Plans must provide a temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) when a beneficiary presents at a pharmacy to request a refill of a non-formulary drug (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) within the first 90 days of their coverage under the new plan. We believe it makes sense to both limit and define the amount of time during which a transition process is applicable to new enrollees. To that end, plans will be required to provide a temporary supply fill anytime during the first 90 days of a beneficiary's enrollment in a plan. Since certain enrollees may join a plan at any time during the year, this requirement will apply beginning on an enrollee's first effective date of coverage, and not only to the first 90 days of the contract year. This 90 day timeframe assists those beneficiaries transitioning from other prescription drug coverage who obtained extended (e.g., 90-day) supplies of maintenance drugs prior to the last effective date of their previous coverage.

30.4.1.4 Edits for Transition Fills

One of our most important goals for a transition process is to ensure that a new enrollee is able to leave a pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays. Part D plans may only apply certain drug utilization management edits during a beneficiary's transition period. Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:

- Edits to help determine Part B vs. Part D coverage

- Edits to prevent coverage of non-part D drugs (i.e. excluded drugs)
- Edits to promote safe utilization of a Part D drug (e.g. Quantity limits based upon FDA maximum recommended daily dose; Early refill edits)

While Part D plans may implement step therapy or prior authorization edits during transition, they may do so only if such edits are resolved at the point of sale. For example, if a prescriber writes a prescription for 5mg tablets at 2 tablets daily, Part D plans might have dose optimization edits in place to require the prescription to be changed to 10mg tablets, one tablet daily. However, during transition, Part D plans would need to allow pharmacies to override this edit if the prescriber will not authorize the change at point of sale. In other words, the beneficiary should leave the pharmacy with sufficient quantity of medication (either 5mg or 10mg tablets) to last the plan allowable days supply, unless the prescriber originally wrote for a lesser days supply. If the dose optimization edit (or any other step therapy/prior authorization edit) is overridden at point of sale for transition purposes only, but not permanently, the beneficiary must be so notified so that he or she can begin the exception process if necessary. As part of their transition process submissions to CMS, plans should describe any edits on transition drugs and their process for resolving those edits at the point of sale.

We note that although Part D plans may implement quantity limits for safety purposes or drug utilization edits that are based upon approved product labeling during a beneficiary's transition period, to the extent that the prescription is dispensed for less than the written amount due to a plan edit, plans must provide refills for that transition supply (at least a 30-day supply in a retail setting and a 90-day supply in a long-term care setting). For example, if a beneficiary presents at a retail pharmacy with a prescription for one tablet per day for 30 days and a plan has a quantity limit edit in place that limits the days supply to 14 per prescription for safety purposes, the beneficiary would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the beneficiary should be entitled to another 14-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

Irrespective of transition, all of these edits are subject to exceptions and appeals. For example, if a quantity limit edit (based upon maximum recommended daily dose) results in the dispensing of a quantity that is less than indicated on the prescription and is less than the plan allowable days supply (as determined by the prescribed daily dose), Part D sponsors must ensure that beneficiaries are made aware of this quantity limit and that an exception is required to obtain a greater quantity. Part D plans must expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

A plan does retain the authority to deny access to quantities or doses during transition (i.e., where clearly articulated safety limits established by the FDA or based upon the same peer reviewed medical literature or well-established clinical practice guidelines

used by the P&T committee in formulary management have been exceeded). Prior to implementing such a denial, a plan should ensure and track that both (1) an initial transition supply has been provided up to the maximum limit and that (2) the plan has assisted the beneficiary or physician in filing an exception and appeal or that an exception and appeal has been processed.

30.4.1.5 New Prescriptions versus Ongoing Medication Therapy

We are aware that it may be difficult for plans to distinguish between new prescriptions for non-formulary Part D drugs and refills for ongoing medication therapy involving non-formulary Part D drugs. For example, some new enrollees may need to switch pharmacies when they enroll in a new Part D plan (or when they enroll in Part D for the first time) and, depending on state law, their prescriptions may not transfer from pharmacy to pharmacy. In other words, some enrollees may need to present at their new network pharmacy with a new prescription for use at that pharmacy, even if that prescription is for ongoing medication therapy. We recognize that it may be difficult for plans to distinguish between ongoing medication therapy and a brand-new prescription for a non-formulary Part D drug. Although plans may attempt to follow up with prescribing physicians and pharmacies to ascertain the status of a prescription presented during the transition period, we clarify that if a plan is unable to make this distinction at the point of sale, it will be required to apply all transition process standards specified by CMS in this document to a new prescription for a non-formulary Part D drug. In other words, a brand-new prescription for a non-formulary drug will not be treated any differently than an ongoing prescription for a non-formulary drug when a distinction cannot be made at the point of sale.

30.4.1.6 Transition Notices

A successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees' medical needs are safely accommodated within a Part D plan's formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, that the plan will cover that drug for the remainder of a the plan year. For this reason, plans must provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules).

Plans will be required to send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This standard is consistent with our requirement that other beneficiary communications, including formulary change notices and explanations of benefits, be sent via U.S. First Class mail. In addition, this notice must be sent to each affected enrollee within three business days of the temporary fill. We believe this turnaround is necessary in order to provide an affected enrollee with sufficient time -- especially in light of our 30-day transition fill policy in the retail setting -- to work with

his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

The notice must include the following elements: (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. As we did in 2006, we will provide plans with a model letter that they may submit to CMS under the file and use certification process. Given that a notice that conforms with our model letter will be generic, we expect that plans will make prior authorization or exception request forms available upon request to both enrollees and prescribing physicians and via a variety of mechanisms -- including by mail, fax, email, and on plan websites. While plans must, at a minimum, send affected enrollees a generic notice, we encourage plans to provide more detailed transition notices -- including the reason for a transition fill, alternative formulary drugs, and any prior authorization or exception request forms a beneficiary will need to effectuate a transition -- to the extent they have that capacity.

In addition, we strongly encourage point-of-sale notification of enrollees about transition supplies by pharmacists. We are working with the pharmacy and drug benefit industry, including the National Council for Prescription Drug Programs (NCPDP), to incorporate a work-around process for using structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. This process would be consistent with the current NCPDP 5.1 standard.

30.4.1.7 Public Notice of Transition Process

As a general matter, we believe plan sponsors must make general information about their transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug best meets their needs on a variety of factors. Matching their current medication list with a Part D plan's formulary may be only one factor in the decision making process. Other factors, such as cost issues and inclusion of the retail pharmacy that they are most familiar with in the plan's network, may bear more weight in the final decision-making process. Having information about a plan's transition process in plan enrollment materials and websites, as well as on the Medicare Prescription Drug Plan Finder, may reassure beneficiaries that there will be procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate. It will also serve to educate advocates and other interested third parties – for example, state Medicaid agencies – about plan transition processes.

We will make available plan transition process information available via a required link from the Medicare Prescription Drug Plan Finder to individual plan websites. This is consistent with the manner in which current enrollees, prospective enrollees, and other stakeholders will be able to access information about plan exception and appeals processes in 2007. We will provide plans with model submission forms so that plan

transition process information is presented consistently from plan to plan. We will provide these model submission forms to plans via our marketing guidelines. We will also require that plans include transition process information in their pre- and post-enrollment materials as appropriate.

30.4.2 General Transition Process

We are asking plans to ensure that they have provided their enrollees who have used a transition benefit with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition. Steps that Plans should consider to ensure a meaningful transition include:

- Analyzing claims data to determine which enrollees require information about their transition supply.
- Contacting those enrollees to ensure they have the necessary information to enable them to switch to a formulary product or as an alternative to pursue necessary prior authorizations or formulary exceptions.
- Increasing staff capacity to respond to an anticipated increase in the volume of formulary exceptions request.
- Increasing call center capacity, including pharmacy help lines, to respond to an anticipated increase in call volume from affected enrollees regarding the plans transition process.
- Making arrangements to continue to provide necessary drugs to an enrollee by extending the transition period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period. For example, in the event that some of the enrollees were enrolled in two plans at the same time and have been re-enrolled into a single existing plan, we would expect the existing Plan to provide a new 30 day transition period in cases where the individual is presenting at a contracted pharmacy under this new plan for the first time.

We understand that many of the Plans have systems in place to trigger a written notice to a member when a plan provides a transitional first fill of a non-formulary drug, and others still may provide instructions – including instructions to contact the plan for further information – through the contracted pharmacies. While plans have flexibility to provide this information in a variety of forms, the instructions to the enrollee must, at a minimum, explain:

- That the transition supply provided is temporary and may not be refilled unless a formulary exception is approved;
- That the enrollee should work with the plan as well as his or her health care provider to identify appropriate therapeutic alternatives that are on the plan's formulary and that will likely reduce his or her costs;
- That the member has the right to request a formulary exception, the timeframes for processing the exception, and the member's right to request an appeal if the plan issues an unfavorable decision; and

- The plan's procedures for requesting a formulary exception.

30.4.3 Current Enrollee Transitions

In addition to circumstances impacting new enrollees who may enter a plan with a medication list that contains non-formulary Part D drugs, other circumstances exist in which unplanned transitions for current enrollees could arise and in which prescribed drug regimens may not be on plan formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, beneficiaries who enter LTC facilities from hospitals are sometimes accompanied by a discharge list of medications from the hospital formulary, with very short term planning taken into account (often under 8 hours). Similar situations may exist, for example, for beneficiaries who are discharged from a hospital to a home; for beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary; for beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; for beneficiaries who end a long-term care facility stay and return to the community; and for beneficiaries who are discharged from psychiatric hospitals with medication regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers must clearly avail themselves of plan exceptions and appeals processes. We have streamlined the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, we make it clear that a Part D plan sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires. In addition, and as described above, current enrollees entering LTC settings from other care settings will be provided emergency supplies of non-formulary drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules.

However, even with these protections, there may exist some period of time in which beneficiaries with level of care changes have a temporary gap in coverage while an exception is processed. For this reason, we strongly encourage plans to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

In addition, we learned in 2006 that many plans were rejecting claims based on early refill edits in cases in which an enrollee was admitted to or discharged from a LTC facility. An early refill edit is a utilization management tool used to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit. For example, if a patient gets a prescription for 30 tablets for a 30 days supply (i.e. 1 tablet daily), but the prescriber changes the dose to 2 tablets daily after only 10 days, it would be inappropriate for a plan to deny as "too soon" a claim for a new prescription with the new dosage because the enrollee will not have enough medication to last until the originally scheduled refill date. Similarly, when an enrollee is admitted to or discharged from a LTC facility, he or she

will not have access to the remainder of the previously dispensed prescription (through no fault of his or her own) and, therefore, plans must allow the enrollee to access a refill upon admission or discharge.

30.4.4 Emergency Supply for Current Enrollees

Since, as a matter of general practice, LTC facility residents must receive their medications as ordered without delay, Part D plans must cover an emergency supply of non-formulary Part D drugs for LTC facility residents as part of their transition process. During the first 90 days after a beneficiary's enrollment, he or she will receive a transition supply. However, to the extent that an enrollee in a LTC setting is outside his or her 90-day transition period, the plan must still provide an emergency supply of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – while an exception is being processed. These emergency supplies of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – must be for at least 31 days of medication, unless the prescription is written by a prescriber for less than 31 days.

30.4.5 Transition Process in the Retail Setting

The minimum transition process standards described in Section 30.3.1 will apply to beneficiaries obtaining their drugs in a retail setting (or via home infusion, safety-net, or I/T/U pharmacies). However, we clarify that, in the retail setting, the one-time, temporary supply of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days. Plans should note that, outside the long-term care setting, such a temporary fill may be a one-time fill only.

30.4.6 Transition Process in the LTC Setting

It is important that the transition process take into account the unique needs of residents of LTC facilities who enroll in a new Part D plan. Residents of LTC facilities are more likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee. In addition, given that a large proportion of LTC facility residents may be dually eligible for both Medicare and full Medicaid benefits, and could be auto-enrolled into the plan without making an affirmative selection based on the individual's existing treatment needs, it is critical that the transition process address access to medications at the filling of the first prescription. When possible, we encourage plan sponsors to ensure that LTC pharmacies in the plan's network that have relationships with LTC facilities work with those facilities prior to the effective date of enrollment to ensure a seamless transition of the facility's residents.

30.4.6.1 Transition Period Immediately After Part D Enrollment for LTC Facility Residents

The minimum transition process standards described in Section 30.4.1 will apply to beneficiaries obtaining their drugs in a long-term care setting. The temporary supply of non-formulary Part D drugs – including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules – for a new enrollee in a LTC facility may be for up to 31 days (unless the prescription is written for less than 31 days). We are requiring up to a 31-day transition supply given that many LTC pharmacies and facilities dispense medications in 31-day increments. However, unlike in the retail setting, plans must honor multiple fills of non-formulary Part D drugs, including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules, as necessary during the entire length of the 90-day transition period.

30.4.7 Transition Extension

A plan may need to make arrangements to continue to provide necessary drugs to an enrollee via an extension of the transition period, on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period. It is equally vital that plans give affected enrollees clear guidance regarding how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period. Until that transition is actually made, however, either through a switch to an appropriate formulary drug, or decision of an exception request, continuation of drug coverage is necessary, other than for drugs not covered under Medicare Part D.

30.5 Provider and Patient Education

A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. See the marketing guidelines on our website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/07_RxContracting_Marketing.asp#TopOfPage for more information on acceptable formulary marketing methods.

Appendix A

Common Acute Care Home Infusion Drugs

Heparin
Parenteral / IV Glucocorticoids
Parenteral / IV 5-Hydroxytryptamine 3 (5-HT3) Antagonists
Parenteral / IV Amino Acids
Parenteral / IV Amino Derivative Penicillins
Parenteral / IV Aminoglycosides
Parenteral / IV Beta-Lactam, Carbapenem
Parenteral / IV Cephalosporin Antibacterials, 1st Generation
Parenteral / IV Cephalosporin Antibacterials, 3rd Generation
Parenteral / IV Cephalosporin Antibacterials, 4th Generation
Parenteral / IV Colistimethate
Parenteral / IV Dextrose in NaCl
Parenteral / IV Electrolytes
Parenteral / IV Extended Spectrum Penicillins
Parenteral / IV Glycopeptide Antibacterials
Parenteral / IV Glycylclyclines
Parenteral / IV Lincomycin Antibacterials
Parenteral / IV Lipids
Parenteral / IV Lipopeptides
Parenteral / IV Loop Diuretics
Parenteral / IV Opioid Analgesics, Long-acting
Parenteral / IV Opioid Analgesics, Short-acting
Parenteral / IV Oxazolidinone Antibacterials
Parenteral / IV Penicillinase-resistant Penicillins
Parenteral / IV Potassium Chloride
Parenteral / IV Quinolones
Parenteral / IV Sodium Chloride
Parenteral / IV Sterile Water
Parenteral / IV Triazole Antifungals
Parenteral / IV Dextrose in Ringers

Part D Drugs/Part D Excluded Drugs

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a "Part D drug" before drawing conclusions from this table. This table does not address B versus D coverage questions.

Product/Drug/Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit (when used for "medically accepted indication"[1] and not covered under Medicare Parts A or B)**	**Comments**
Advicor®	Yes	See Commercially Available Combination Product Policy – Section 10.3
Agents when used for anorexia, weight loss, or weight gain	No	Prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded under such exclusion categories.
Agents when used for cosmetic purposes or hair growth	No	Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetic.
Agents when used for symptomatic relief of cough and colds	No	All agents when used for symptomatic relief of cough, cold, or cough and cold are excluded from Part D
Antihistamine/Decongestant Combinations (RX)	Yes, except when being used for symptomatic relief of cough and cold	
Barbiturates	No	
Benzodiazepines	No	
Blood glucose testing strips	No	NOT directly associated with injection of insulin
Electrolytes/Replenishers: • *Potassium • Sodium • Calcium • Magnesium	Yes	*Potassium Iodide products are excluded from Part D as Iodine products (minerals) because they are not used for potassium supplementation
Extemporaneous Compounds, including sterile compounding of IV's and TPN	Yes, but only costs for Part D drug components may be billed under Part D	Dispensing fee may include labor costs associated with mixing a compounded drug product that contains at least one Part D drug component Part D drug components used solely as vehicles in a compound may be covered under Part D (e.g. D5W, Normal Saline)
Fioricet® (Bultalbital, APAP, Caffeine)	No	See Commercially Available Combination Product Policy Section 10.3
Fioricet® with Codeine	Yes	See Commercially Available Combination Product Policy Section 10.3

[1] Medically Accepted Indication for purposes of Part D is an FDA labeled indication or an indication supported by citation in either the American Hospital Formulary System (AHFS), USP-DI, or Drugdex.

Part D Drugs/Part D Excluded Drugs

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a "Part D drug" before drawing conclusions from this table. This table does not address B versus D coverage questions.

Product/Drug/Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit (when used for "medically accepted indication"[1] and not covered under Medicare Parts A or B)**	**Comments**
Fiorinal® (Butalbital, ASA, Caffeine)	No	See Commercially Available Combination Product Policy Section 10.3
Fiorinal® with Codeine	Yes	See Commercially Available Combination Product Policy Section 10.3
Fosamax plus D	Yes	See Commercially Available Combination Product Policy Section 10.3
Guaifenesin (RX)	Yes	
Heparin/Saline Flushes	No	CMS clarified in the preamble to the final rule that although heparin is a Part D drug, a heparin flush is not used to treat a patient for a medically accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. It would therefore not be a Part D drug when used in a heparin flush. (70 FR 4232)
Injectable or IV Iron products such as Iron Dextran, Iron Sucrose and Sodium ferric gluconate	No	Prescription vitamin/mineral product
Insulin	Yes	
Insulin syringes	Yes	Syringes are NOT covered for injection of other Part D drugs
IV Solutions for hydration therapy	Yes	
Klonopin® (Clonazepam)	No	Benzodiazepine
Lancets	No	NOT directly associated with injection of insulin
Less-than-effective DESI Drugs (and those drugs identical, related or similar)	No	
Leucovorin Calcium	Yes	
Librax®	No	Less-than-effective DESI drug
Limbitrol® (Amitriptyline/chlordiazepoxide)	Yes	See Commercially Available Combination Product Policy Section 01.3
Megestrol Acetate and Growth Hormone when used for AIDS wasting and cachexia	Yes	Prescription drug products that otherwise satisfy the definition of Part D drug are Part D drugs when used for AIDS wasting and cachexia if these conditions are "medically accepted" indications, as defined by section 1927(k)(6) of the Social Security Act (SSA), for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or

Part D Drugs/Part D Excluded Drugs

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a "Part D drug" before drawing conclusions from this table. This table does not address B versus D coverage questions.

Product/Drug/Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit (when used for "medically accepted indication"[1] and not covered under Medicare Parts A or B)**	**Comments**
		agents used for cosmetic purposes, and therefore such products cannot be excluded from the Medicare Prescription Drug Benefit by reference to section 1927(d)(2) of the SSA.
Methadone	Yes, except when indicated for the treatment of opioid dependence	A Part D drug is partially defined as "a drug that may be dispensed only upon a prescription". . . . Consequently, Methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy.
Primidone (Mysoline®)	Yes	NOT considered a barbiturate
Nonprescription/Over-the-counter (OTC) drugs [2]	No, except Insulin and supplies associated with the injection of insulin	Supplies associated with the injection of insulin include syringes, alcohol wipes, insulin pens and pen needles, gauze, and alcohol
Omacor®	Yes	
Phenobarbital	No	Barbiturate
PhosLo®	Yes	
Polysaccharide Iron Complex	No	Prescription vitamin/mineral product
Prescription niacin products	Yes	Prescription niacin products are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program.
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations **Examples**: • B vitamins (Folic Acid, Cyanocobalamin) • Vitamin K (phytonadione)	No	

[2] Part D plans may include OTC drugs in step therapy protocols as part of their cost effective drug utilization management program. However, OTC drugs included in these step therapy protocols are considered administrative costs, not Part D drugs.

Part D Drugs/Part D Excluded Drugs

This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a "Part D drug" before drawing conclusions from this table. This table does not address B versus D coverage questions.

Product/Drug/Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit (when used for "medically accepted indication"[1] and not covered under Medicare Parts A or B)**	**Comments**
• Vitamin D (ergocalciferol and cholecalciferol) • Zinc (sulfate, acetate) • Iron • Iodine • Multivitamin additives for parenteral nutrition		
Smoking cessation drugs (OTC)	No	
Smoking cessation drugs (RX)	Yes	
Sterile Saline/water for Irrigation	Yes	
Suboxone®, Subutex®	Yes	
Vitamin D Analogs (Calcitriol, doxercalciferol, paricalcitol, and dihydrotachsterol)	Yes	NOT considered prescription vitamins

MEDICARE PART B VERSUS PART D COVERAGE ISSUES

This document is not a statement or promise of coverage, but rather a discussion of when something *may* be covered under Parts A, B or D, if all other coverage requirements are met. For example, a Part D drug must still be medically necessary

Introduction

This document provides an overview of outpatient prescription drug coverage policies under Medicare. Beneficiaries who are inpatients of hospitals or skilled nursing facilities during covered stays may receive drugs as part of their treatment. Typically, the payment for drugs is bundled into the Medicare Part A payments made to these types of facilities.[1] Under the hospice benefit, beneficiaries receive drugs that are medically necessary for symptom control or for pain relief. In general, references are seen to five major categories of Medicare Part B drug spending: 1. drugs billed by physicians and typically provided in physicians offices (such as chemotherapy drugs); 2.drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; 3.drugs billed by pharmacy suppliers and self-administered by the patient (such as immunosuppressive drugs and some oral anti-cancer drugs); 4. Separately billable drugs provided in Hospital Outpatient Departments; and 5. Separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO). Regional differences in Part B coverage policies for drugs can occur in the absence of a national coverage decision. A drug for which coverage is available under Part A or Part B, as it is being "prescribed and dispensed or administered" with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage.

Medicare Part A and Part B Covered Drugs

Part A/B Covered Drugs Set by Statute

Traditional Medicare (Part A/B) does not cover most outpatient prescription drugs. Medicare bundled payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is usually limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered.

[1] If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled in the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g. flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.

Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:

Durable Medical Equipment (DME) Supply Drugs. These are drugs that require administration by the use of a piece of covered 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 in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). 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. some chemotherapeutic agents).

Immunosuppressive Drugs. Drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.

Hemophilia clotting factors. Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.

Oral Anti-Cancer Drugs. Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician's professional service.

Oral Anti-emetic Drugs. Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.

Pneumococcal vaccine. The vaccine and its administration to a beneficiary if ordered by a physician.

Hepatitis B vaccine. The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.[2]

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[2] High risk groups currently identified include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B Virus (HBV) carrier; homosexual men; illicit injectable drug abusers. Intermediate risk groups include: staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

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Influenza vaccine. The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

Antigens. These 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.

Erythropoietin (EPO). EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.

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.

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.

Part B Covered Drugs in the Context of a Professional Service

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 as "incident to" a physician's professional service. The statute limits coverage to drugs that are not usually self-administered.[3]

Separately Billable ESRD Drugs. Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs are 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.

Separately billable drugs provided in Hospital Outpatient Departments. For Calendar Year 2005, Medicare continues to pay separately for drugs, biologicals and radiopharmaceuticals whose median cost per administration exceeds $50, while packaging the

[3] If a drug is not self-administered by more than 50 percent of Medicare beneficiaries, it is considered "not usually self-administered".

cost of drugs, biologicals, and radiopharmaceuticals whose median cost per administration is less than $50 into the procedures with which they are billed.

Drugs covered as Supplies or - "Integral to a Procedure." Some drugs are covered as supplies that are an integral part of a procedure which is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. Other examples of drugs covered under the "integral to a procedure" provision include eye drops administered before cataract surgery.

Blood. Medicare does make separate payment for blood and blood products and these products are regulated as biological agents by the FDA.

Drugs furnished as a part of a service in these provider settings. 1. Drugs packaged under the Hospital Outpatient Prospective Payment System; 2. Drugs furnished by ESRD facilities and included in Medicare's ESRD composite rate; 3.osteoporosis drugs provided by home health agencies under certain conditions; 4. Drugs furnished by Critical Access Hospitals' (CAH) Outpatient Departments; 5. Drugs furnished by a Rural Health Clinic (RHC); 6. Drugs furnished by Federally Qualified Health Centers (FQHC); 7. Drugs furnished by Community Mental Health Centers (CMHC); 8. Drugs furnished by Ambulances; 9. Separately billable drugs provided in Comprehensive Outpatient Rehabilitation Facilities (CORF).

Part D Covered Drugs

Definition of a Part D Covered Drug

A Part D covered drug is available only by prescription, approved by the Food and Drug Administration (FDA) (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, and vaccines licensed under section 351 of the Public Health Service Act. The definition also includes "medical supplies associated with the injection of insulin (as defined in regulations of the Secretary)." We define those medical supplies to include syringes, needles, alcohol swabs, and gauze.

Part D Excluded Drugs

The definition of a covered Part D drug excludes any drug for which as prescribed and dispensed or administered to an individual, payments would be available under Parts A or B of Medicare for that individual, even though a deductible may apply.

In addition, the definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:

1. Agents when used for anorexia, weight loss, or weight gain.
2. Agents when used to promote fertility
3. Agents when used for cosmetic purposes or hair growth.
4. Agents when used for the symptomatic relief of cough and colds
5. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
6. Nonprescription drugs
7. Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale
8. Barbiturates
9. Benzodiazepines

While these drugs or uses are excluded from basic Part D coverage, drug plan sponsors can generally include them as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug. Because non-prescription drugs do not otherwise meet the definition of a Part D drug, they may not be included as part of supplemental benefits; however, under certain conditions as part of a plan utilization management program (including a step-therapy program), non-prescription drugs can be provided at no cost to enrollees. The cost of these drugs to the plan would be treated as administrative costs under such programs.

Other Resources

1. Medicare Benefit Policy Manual, Chapter 15. "Covered Medical and Other Health Services. Chapter 15, Section 110
2. Medicare Claims Processing Manual, Chapter 17 Drugs & Biologicals, 80.5 Self-Administered Drugs. Chapter 20, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
3. *Reference Guide for Medicare Physician & Supplier Billers, Helping Front Office Personnel Navigate Medicare Rules for Part B Claims Processing*. MedLearn Matters, First Edition – April 2004.
4. O'Sullivan, Jennifer, Congressional Research Service Report RL30819, *Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues.*
5. Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates; Final Rule 42 CFR Part 419, Federal Register/Vol. 69, No. 219/Monday, November 15, 2004/Rules and Regulations

6. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar year 2005; Final Rule. 42 CFR Part 403,405,410 et al. Federal Register/Vol. 69, No219/Monday, November 15, 2004/Rules and Regulations
7. U.S. General Accounting Office. *Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices.* Testimony by Laura Dummit, before Subcommittee on Health, Senate Committee on Finance, March 14, 2002.

ATTACHMENT I

Part B Drugs and Part D Coverage Chart

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.

- In addition, there are 13 categories of drugs for which separate payment is made under Part B[4], including: drugs furnished "incident to" a physician service; separately billable ESRD drugs; separately billable drugs provided in hospital outpatient departments; durable medical equipment (DME) supply drugs; 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 provide in the home.[5]

The following chart groups the various categories of Part B coverage according to the extent to which they present some ambiguity for billing entities and/or Part D plans with regard to whether coverage should be under Part B or Part D. This ambiguity has different implications for Prescription Drug Plans (PDPs) and for Medicare Advantage-Prescription Drug (MA-PD) Plans (including PACE plans and Section 1876 Cost plans which are treated similarly to MA-PDs). For PDPs, the plan sponsor needs to

[4] If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled into the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g. flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.

[5] Medicare does make separate payment for blood and blood products under Part A and Part B. Although these products are regulated as biologicals by FDA, they are not administered in a context that would not be covered under Part A or Part B. Therefore, these products are not Part D drugs. As a result, they are not included in this discussion.

determine whether it should make any payment. For MA-PDs, the MA organization needs to determine whether a payment should be assigned to its Part D spending or to its spending for Part B services.

A. Situations in which a billing entity would have to decide whether for a given drug (NDC) to bill Part B or Part D based on characteristics of beneficiary or medical use of the drug.		
Relationship between Part B and Part D Coverage	**Categories of Separately Billable Part B Drugs**	**Comments**
1. The same drug (NDC) dispensed by a **pharmacy** may be covered under Part B or Part D depending on the characteristics of the beneficiary	Drugs used in Immunosuppressive therapy for a transplant covered under Medicare.	Pharmacists would bill Part B or the individual's Part D plan based on information received from the individual or the Part D plan. Part B would be billed if the individual had a Medicare-covered transplant; otherwise, the Part D plan would be billed. (Part D plan eligibility systems could contain a marker for members who had a Medicare covered transplant. This information could come from a question included on the Part D plan's enrollment or COB survey form.) In determining whether to pay for an immunosuppressive drug under Part D, it would not be appropriate for a Part D plan to institute a general policy of requiring a Part B claim rejection, as a substitute for maintaining information on transplant status and paying claims based on that information. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. Instead a prior authorization requirement would be appropriate.
2. The same drug (NDC) provided by an **infusion/DME supplier** may be covered under Part B or Part D depending on the characteristics of the beneficiary or method of administration	a. Parenteral nutrition (for individuals with a non-functioning digestive tract)	The supplier would need to know whether the therapy was being provided because of a non-functioning digestive tract. If so, Part B would be billed. Otherwise this would be a Part D drug. It would not be appropriate for PDPs to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. However, if a PDP had evidence indicating that a

		particular claim for parenteral nutrition should be covered under Part B, it would be reasonable to require a rejection by Part B before processing in this case.
	b. Infusible DME supply drugs	In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g. IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B Home Health benefits, under Medicaid, or from secondary commercial health benefits. As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DMERC. In the case of a beneficiary, in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D. (see Attachment II, **INFUSION DRUGS**, Question 3 for other facilities which cannot be considered a beneficiary's "home" for DME purposes.) The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an

		infusion pump (e.g. IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DMERC. Therefore, determinations about PDP payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DMERC policy should be based on the question of whether the drug is on the plan formulary.
	c. Intravenous immune globulin (IVIG) provided in the home for individual with diagnosis of primary immune deficiency disease	The supplier would bill Part B if the diagnosis is primary immune deficiency disease. IVIG provided in the home for other diagnoses would be a Part D benefit. As discussed above, it would not be appropriate, as a general rule, for PDPs to require a rejection of a claim under Part B before processing a Part D claim. Prior authorization programs could be used to ensure medical necessity in accordance with Plan policy.
3. The same drug (NDC) dispensed by a **pharmacy** may be covered under Part B or Part D depending on how the drug is used in treatment and the medical condition for which the drug is being prescribed.	a. Certain oral chemotherapy agents used in cancer treatment for which there is an infusible version of the drug.	Pharmacists would need to determine the reason for treatment. If related to cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed. Pharmacists would bill the Part D plan for all other oral chemotherapy agents. To the extent that a Part B-covered oral anti-cancer drug has no other medically accepted indication besides cancer treatment, Part D plans should not include these drugs on their formularies because of Part B coverage. For the drugs that have other medically accepted indications, prior authorization programs or other mechanisms to obtain diagnostic information could be used to ensure appropriate payment.
	b. Oral anti-emetics used in cancer treatment as a full replacement for intravenous treatment.	2. Pharmacists would need to determine the reason for treatment. If both related to cancer treatment and a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, the Part D plan should be

		billed. Note: In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used "as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen." If based on a prior authorization program or other mechanism to obtain diagnostic information, a PDP determined that a) a Part B-covered oral anti-emetic was being billed, and b) the drug was being furnished in the context of cancer treatment for use within 48 hours of cancer treatment, the PDP should deny payment. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than the effects of cancer treatment, would be Part D drugs.
4) The same vaccine may be covered under Part B or Part D depending on the characteristics of the beneficiary	Hepatitis B vaccine for individuals at high or intermediate risk.	Physicians would need to determine the level of risk of the individual. If the individual is at high or intermediate risk, Part B would be billed. For all other individuals,. prior authorization programs could be used to ensure medical necessity in accordance with Plan policy. Beneficiaries in PDPs would generally submit a paper claim for Part D reimbursement, since a vaccine dispensed in a physician's office would not be billable by means of routine pharmacy electronic claims systems.
B. Situation where the form of the drug determines where it is covered.		
Relationship between Part B and Part D Coverage	**Categories of Separately Billable Part B Drugs**	**Comments**
The same drug provided by a **DME supplier** or a **pharmacy** may be covered under Part B or Part D depending on its form (i.e. for use in nebulizer or in metered dose inhaler)	Inhalation DME supply drugs	Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulized administration, they would be Part D drugs.

		In the case of a beneficiary, in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D. (see Attachment II, **INFUSION DRUGS**, Question 3 for other facilities which cannot be considered a beneficiary's "home" for DME purposes.)
C. Situations where Part B coverage is in the context of another service.		
Relationship between Part B and Part D Coverage	**Categories of Separately Billable Part B Drugs**	**Comments**
The same drug (NDC) dispensed by a **pharma**cy is covered under Part B if provided as part of a service in a provider, physician's office or home.	1. Drugs furnished "incident to" a physician service 2. Separately billable ESRD drugs 3. Separately billable drugs in HOPDs 4. Separately billable drugs in CORFs 5. Drugs packaged under the Outpatient Prospective Payment System (OPPS) 6. Drugs furnished by	Generally, if a beneficiary presents at a pharmacy with a script it would be a Part D drug. The availability of Part B coverage in a provider setting or physician's office should not result in a refusal of coverage under Part D for drugs dispensed by a pharmacy. This is the case because coverage is not available under Part B as the drug is being "prescribed and dispensed or administered" with respect to the individual. Thus, for example, while Part B covers certain injectables provided "incident to" a physician services, injectables dispensed by a pharmacy are not being "furnished" by a physician and would be Part D drugs. PDPs should deny claims submitted by members for Part B-covered injectables if they are administered in a physician office from a physician's supply.

	End-Stage Renal Disease (ESRD) facilities and included in Medicare's ESRD composite rate 7. Osteoporosis drugs provided by home health agencies under certain conditions 8. Drugs furnished by critical access hospitals' outpatient departments 9. Drugs furnished by rural health clinics 10. Drugs furnished by federally qualified health centers 11. Drugs furnished by community mental health centers 12. Drugs furnished by ambulances.	PDPs can subject injectables and infusables that would be covered under Part B as "incident to" a physician service, to a prior authorization program. To the extent that the sponsor determines based on medical society guidelines and other medical literature that there exist serious safety concerns such that it would go against accepted medical practice for a particular injectable or infusable to be dispensed directly to a member, the claim can be denied as not "reasonable." Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, however, there are very few instances when an injectable or infusable drug could not be reasonably dispensed directly to the patient.
D. Completely unambiguous situations.		
Relationship between Part B and Part D Coverage	**Categories of Separately Billable Part B Drugs**	**Comments**
1) Unique drugs never dispensed by a	Non-DME drugs covered	This category of drugs is those used for diagnostic or therapeutic

pharmacy.	as supplies (including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media.)	purposes in a provider or physician office setting. We would assume that these drugs are not dispensed by pharmacies.
2) Drugs that **would not** be covered under Part D because of Part B coverage.	1. Blood clotting factors 2. Antigens 3. Pneumococcal and influenza vaccines	These categories would not be a Part D benefit and should not be included on a Part D plan's formulary.

ATTACHMENT II

Part B v. Part D Drug Q's and A's

A. EXCLUDED DRUGS

Question 1 - Are certain therapeutic drug categories excluded from Part D?

Answer 1 - There are certain drugs or uses of drugs that are excluded from the definition of a Part D drug. This means that they cannot be provided as part of basic coverage. These exclusions include:

- benzodiazepines,
- barbiturates,
- drugs for anorexia, weight loss, or weight gain,
- drugs used to promote fertility,
- drugs used for cosmetic purposes or for hair growth,
- drugs used for symptomatic relief of cough and colds,
- prescription vitamins and mineral products, except prenatal vitamins and fluoride preparation products,
- non-prescription drugs, and
- drugs for which the manufacturer seeks to require as a condition of purchase that associated tests and monitoring services be purchased exclusively from the manufacturer or its designee.

While these drugs or uses are excluded from basic Part D coverage, drug plan sponsors can generally include them as part of supplemental benefits to the extent they otherwise meet the definition of a part D drug. Because non-prescription drugs are not otherwise considered part D drugs, they cannot be included in supplemental benefits. However, under certain conditions—as part of plan utilization management (step-therapy) programs—non-prescription drugs can be provided at no cost to enrollees. The cost of these drugs would be treated as administrative costs under such programs.

B. EXCLUSIONS RELATED TO MEDICARE COVERAGE UNDER PART A OR PART B

Question 1 – Should drug plans deny claims for drugs covered under Part A or Part B of Medicare?

Answer 1 – Drugs, or uses of drugs, for which coverage is available under Part A or Part B are excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage. Unlike the list of excluded drugs described above, these drugs, or uses of drugs, cannot be included in supplemental coverage.

There are two important considerations in determining whether a claim to Part D can be denied based on the availability of coverage under Part A or Part B of Medicare.

- First, the exclusion from the definition of a Part D drug for drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being "prescribed and dispensed or administered" with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs and coverage generally cannot be determined based solely on the drug itself. Since most Part B drug coverage is available in a provider setting or physician's office rather than as drugs dispensed by pharmacists, there are very limited situations when a drug claim submitted by a pharmacy should be denied based on the availability of coverage under Part A or Part B.

- Second, , to the extent a drug could be covered under part B as prescribed and dispensed or administered, plan sponsors should view coverage as "available" under Part B regardless of whether or not an individual is actually enrolled in Part B.

Question 2– Can a drug plan require that coverage be denied under Part A or Part B before making payment under Part D?

Answer 2 – Generally, no. However, an exception could be made if a PDP had evidence that a particular claim for parenteral nutrition should be covered under Part B. In this case, it would be reasonable to require a rejection by Part B before processing. In other limited instances, prior authorization programs may be necessary to determine whether the diagnosis of the individual or the particular use of a drug is consistent with Part D coverage, but it would not be appropriate to routinely require a denial from Part A or Part B before making payment in lieu of prior authorization. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 3 - What happens if a drug plans makes payment for a drug and later determines that the drug was covered under Part B as prescribed and dispensed or administered?

Answer 3 - If the drug as prescribed and dispensed or administered was covered under Part B on that day, the payment by the plan would have been in error and it should seek recovery from the billing entity, which should bill Part B instead.

Question 4 - In the case of a newly approved drug that may be covered under one of the Part B benefit categories, can a drug plan defer a coverage decision until Part B makes a decision?

Answer 4 - No. Once a drug is approved by the FDA it is a Part D drug. While it is not automatically a covered Part D drug, that is, it may not be included on a plan formulary, a member could request coverage on an exception basis. Plan sponsors would have to follow the processes and timeframes set forth in regulations with regard to such requests.

For Medicare Part B coverage, a determination has to be made as to whether the approved drug fits in a benefit category (e.g. a drug covered as a supply of an external infusion pump used at home). In the vast majority of cases these determinations are delegated to the individual carriers. If a drug has a Medicare Part B benefit category and the drug is being "prescribed and dispensed or administered" as covered under Part B, the drug is no longer a Part D drug.

Question 5 - How will drug plans determine whether a drug is covered under Part B?

Answer 5 - First, it is important to keep in mind that in most cases Part B drug coverage should not impact payment decisions by drug plans since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy.

Payment for a particular drug can be denied only if there is Part B coverage as the drug is prescribed and dispensed or administered. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the drug plan would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the drug plan and the Medicare Part B carrier with jurisdiction in that geographic area for that drug.

With regard to new drugs, as decisions are made nationally or by individual carriers, this information will be available on the CMS and carrier web sites.

INFUSION DRUGS

Question 1 - Since Part B covers infusion drugs in the home, can a drug plan sponsor reject any claim for home infusion?

Answer 1 – No. Part B coverage is generally limited to a number of drugs that require the use of an infusion pump in the home. Any agents administered in the home via IV drip or push injection would be covered under Part D. This could include the same drugs that are covered under Part B when furnished through the use of an infusion pump.

Question 2 – Does Part B covers drugs that require an external infusion pump in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, drugs that require an external infusion pump are not covered under Part B under those circumstances because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose.

Question 3 - What other facilities cannot be considered the beneficiary's "home" under the law for purposes of receiving the Medicare DME benefit?

Answer 3 – In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e. neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

Question 4 - If the infusion services are furnished in a outpatient provider setting, can a drug plan sponsor deny a claim?

Answer 4 – Yes. If a physician office or hospital OPD bill for infusion administered in those settings, the claim should always be denied because of coverage in those settings under Part B.

Question 5 – Since Part B covers intravenous immune globulin (IVIG) provided in the home, should drug plans deny claims for this drug?

Answer 5 – It depends. Part B coverage for IVIG in the home is for individuals whose diagnosis is primary immune deficiency disease. Part D would provide coverage for IVIG in the home for all other medically accepted indications. Prior authorization requirements could be used to ensure appropriate payment in accordance with Plan medical necessity criteria. It would not be appropriate to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 6 – Since Part B covers parenteral nutrition under certain circumstances, should drug plans deny these claims?

Answer 6 – It depends. Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. So if parenteral nutrition is being provided based on this condition, the claim should be denied. For all other medically accepted indications, coverage would be under Part D. Prior authorization programs could be used to ensure appropriate payment. As a general policy, it would not be appropriate to require a rejection of a claim under Part B before processing a Part D claim. However, if a PDP had a reasonable basis for assuming that a particular claim would be covered under Part B, it could require a rejection by Part B before processing.

ORAL ANTI-CANCER DRUGS

Question 1 - With regard to oral anti-neoplastics, we understand that if they have an IV form, they are covered under Part B. It is our thinking then, that we could exclude those that are used solely for cancer under this premise since they would be covered under Part B.

Answer 1 – Yes. Drug plans should not include on their formularies the oral anti-cancer agents covered by Part B whose only medically accepted indication is as an anti-cancer agent. They should always deny claims for these drugs. For the drugs that have other medically accepted indications, drug plans should deny claims for these drugs when used for cancer treatment but when these drugs are used for other indications they would be Part D drugs. The use of the drug could be determined through a prior authorization program.

ORAL ANTI-EMETICS

Question 1 - Will Part B coverage of oral anti-emetics move to Part D in January 2006?

Answer 1 - There is no change in Part B coverage of oral anti-emetics on January 1, 2006. The only change is that coverage would become available under Part D for medical uses that are not covered under Part B.

Before billing either Part B or Part D, pharmacists would need to determine the reason for treatment. If it is related to cancer treatment and is a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, Part D should be billed. In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used "as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen."

If (based on a prior authorization program) a PDP determines that a Part B-covered oral anti-emetic drug is being billed, and that the drug is being furnished in the context of cancer treatment for use within 48 hours of such treatment, the PDP should deny payment since coverage is available under Part B. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than treatment of the effects of cancer treatment, would be Part D drugs.

IMMUNOSUPPRESSANTS

Question 1 - Will Part B coverage of immunosuppressants move to Part D in January 2006?

Answer 1 - There is no change in Part B coverage of immunosuppressants on January 1, 2006. The only change is that coverage would become available under Part D for uses not covered under Part B.

Pharmacists would bill Part B or the individual's PDP based on information received from the individual or from the drug plan. Part B would be billed if the individual had a Medicare covered transplant; otherwise, the Part D plan would be billed.

INJECTABLES

Question 1 - Can claims submitted by pharmacies for injectable drugs be denied based on Part B coverage in a physician office "incident to" a physician service?

Answer 1 – No. The exclusion from the definition of a Part D drug of drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being "prescribed and dispensed or administered" with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs. As a result, coverage cannot generally be determined based solely on the drug itself.

The fact that an injectable is covered under Part B in a physician's office or hospital outpatient department or other provider setting does not mean that these drugs should be excluded from drug plan formularies, or that a drug plan can deny a claim from a pharmacy based on availability of Part B coverage in a physician's office. If, however, a member submits an out-of-network claim for an injectable drug administered in-office from a physician's supply, and this drug is covered in that setting by the Part B carrier for that area, such a claim should be denied by the PDP based on Part B coverage. (Of course, an MA-PD plan would not deny such a claim, but rather pay it under the A/B benefit.)

Question 2 - An injectable drug that a Medicare carrier considers to be usually not self-administrable (e.g. injectable chemotherapy drugs) can only be covered under Part B as "incident to" a physician service if it is obtained by a physician and administered as part of a physician service. Can Part D plan sponsors require prior authorization for these medications when dispensed by a pharmacy? If the sponsor determines that the drug will be administered in a physician office, can the sponsor deny the claim because the practice of the patient taking the drug to the physician's office for administration is unsafe and because coverage is available under Part B if the physician obtained and administered the drug?

Answer 2 - Part D plan sponsors determine the scope of their own prior authorization programs subject to CMS review to ensure that such programs have a sound medical basis and do not discriminate against beneficiaries with certain medical conditions.

To the extent that a sponsor's prior authorization program applies to injectables and infusables that would be covered under Part B as "incident to" a physician service, and the sponsor determines based on medical society guidelines and other medical literature that there exist serious safety concerns such that it would go against accepted medical practice for a particular injectable or infusable to be dispensed directly to a member, the claim can be denied as not "reasonable." Thus, the dispensing of that particular drug to that member may be excluded by the plan under Section 1862(a)(1)(A) of the Social Security Act as applied to Part D under 1860D-2(e)(3)(A) of the Act. This same safety concern would not exist, however, if the claim for the drug was being submitted by an infusion supplier.

Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, there are very few instances when an injectable or infusable drug could not be reasonably dispensed directly to the patient. All drugs are in some sense hazardous. This is not a unique characteristic of injectables and infusables.

Some situations that would present safety concerns in dispensing directly to a patient who is transporting the drug to a physician's office for administration include:

- The drug itself presents a bona fide public safety hazard (e.g. highly radioactive substance) that requires chain of custody handling using persons of special qualifications.

- The drug requires special handling to preserve biologic activity and the patient is incapable or unwilling to do so. (For instance, a vaccine that must be kept frozen could be a problem if the patient had to transport it a long distance in summer heat.)

- The patient presents a high risk of diversion or inappropriate use. (For instance, giving a heroin addict a vial of morphine.)

- The patient has demonstrated unreliability, aversion, or unwillingness in transporting drugs to his doctor's office. (For instance, with respect to dispensing injectable psychiatric meds.)

In the absence of a serious safety concern based on the individual situation, however, there is no basis for denying a prescription presented at a pharmacy based on the availability of Part B coverage in another setting (e.g. physician office).

Finally, it is our understanding that the practice of "brown-bagging" drugs is opposed by medical societies. We will urge them to reinforce this message with the start of the Part D program.

Question 3 – Most Medicare Advantage plans treat most non-self-injectables as a medical benefit. Beginning January 1, 2006, do they have to treat them as a Part D benefit?

Answer 3 - If an injectable drug was previously covered under Part B in a provider or physician office setting, it will continue to be covered under Part B in those settings. If it was previously not covered in those settings (e.g. determined by the carrier to be usually self-administered), then it will need to be covered under Part D. In addition, claims for non-Part-B-covered injectables whether usually self-administered or not, when dispensed and submitted by pharmacists could be covered under Part D. However, Part D plans could establish medical necessity criteria for limiting coverage of injectable drugs in physician offices.

Question 4 - What are drug plan sponsors to do if their region includes multiple carrier areas and these carriers have differing policies with regard to injectable drugs?

Answer 4 – A PDP sponsor will have to modify its coverage based on the variation in Part B coverage across carrier areas within its region. That is, assume that there are two carrier areas within a PDP region, Carrier A and Carrier B. Further assume that Carrier A covers injectable X when furnished in a physician office but Carrier B does not. As a result of this difference in Part B coverage, injectable X is a Part D drug when furnished in a physician office for members residing in Carrier B's area, but not in Carrier A's area. In either area, injectable X would be covered under Part D if dispensed by a pharmacy.

For MA-PD plans, rules for selecting local coverage determinations apply. That is, if a local MA plan's service area includes more than one carrier area, the plan may seek approval from CMS to apply uniformly to all of the plan's enrollees local coverage policies that are the most beneficial to enrollees. Regional MA plans can select a set of local coverage policies to apply uniformly to their enrollees without CMS pre-approval. In either case, if the selected carrier covers injectable X, the MA-PD would treat injectable X as a basic A/B benefit. If the selected carrier does not cover injectable X, the MA-PD would treat it as a Part D drug.

Question 5 –What about new injectable drugs?

Answer 5 - As new injectables are approved by FDA, Part B carriers or CMS would continue to make coverage decisions regarding drugs provided incident to a physician service based on whether the drug is "not usually self-administered." Injectables not covered under Part B as incident to a physician service would become Part D drugs. However, there is no requirement for Part D plans to provide coverage of non-Part-B-covered drugs in the physician office setting if the drugs can be safely self-administered and there is no medical necessity for administration in that setting.

INHALATION DRUGS

Question 1 - Can claims submitted by a pharmacy for inhalation drugs delivered through metered-dose inhalers be denied based on Part B coverage of inhalation drugs used with a nebulizer?

Answer 1– No. Since there currently is no coverage under Part B for inhalation drugs delivered through metered-dose inhalers and dispensed by a pharmacy, these drugs would be covered under Part D.

Question 2 – Does Part B covers inhalation drugs used with a nebulizer in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, inhalation drugs used with a nebulizer are not covered under Part B under those circumstances because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. (See list above (**INFUSION DRUGS**, Question 3) for other facilities which cannot be considered a beneficiary's "home" for DME purposes

VACCINES

Question 1 – Will all vaccines be covered under Part D effective January 1, 2006?

Answer 1 – No. If a vaccine was previously covered under Part B, it will continue to be covered under Part B. If it was previously not covered, then it will need to be covered under Part D. Pneumococcal and influenza vaccines are not covered under Part D because of Part B coverage. Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it would covered under a Part D benefit. All other currently available vaccines and all future vaccines would be covered under Part D, but could be subject to Plan prior authorization requirements to determine medical necessity.

Question 2- If a drug plan sponsor determines through a prior authorization program that a Hepatitis B vaccine is going to be administered by a physician can the drug plan sponsor deny the claim based on Part B coverage in the setting?

Answer 2 – No. Since the Part B benefit for Hepatitis B vaccine is separate from the "incident to" benefit, the determination about whether it is a Part D drug depends solely on characteristics of the beneficiary. However, if the plan sponsor determines based on Medicare Part B guidelines that the individual is at high or medium risk for Hepatitis B, the claim should be denied. For all other individuals, the vaccine would be a "Part D drug", and would be covered unless the plan had otherwise established medical necessity criteria for the vaccine as part of its approved prior authorization program In which case, only low risk individuals who meet the plan's criteria would be eligible to receive the vaccine.

Question 3 - Medicare Part B covers hepatitis B vaccine for high and intermediate risk groups if ordered by a doctor of medicine or osteopathy, how are these groups defined?

Answer 3 – The high risk groups for whom vaccination is covered include:

- Individuals with End stage renal disease (ESRD)
- Individuals with hemophilia who received Factor VIII or IX concentrates
- Clients of institutions for individuals for the mentally handicapped
- Persons who live in the same household as a hepatitis B Virus (HBV) carrier
- Homosexual men
- Illicit injectable drug abusers

Intermediate risk groups include:

- Staff in institutions for the mentally handicapped
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

ANTIGENS

Question 1 – If a pharmacy submits a claim for antigens should a drug plan make payment?

Answer 1 – No. Antigens are covered only under Part B.

BLOOD CLOTTING FACTORS

Question 1 – If a pharmacy submits a claim for blood clotting factors should a drug plan make payment?

Answer 1 – No. Blood clotting factors are covered under Part A and Part B.

OFF-LABEL INDICATIONS

Question 1 - Describe how drugs used for off-label indications will be covered under Part D. My understanding is that coverage for off-label use is less liberal under Part D compared to Part B.

Answer 1 - A prescription drug is a Part D drug only if it is for a medically accepted indication as defined in the Medicaid statute. This definition includes uses supported by a citation included, or approved for inclusion, in one of four compendia. These are:

- American Hospital Formulary Service Drug Information
- United States Pharmacopeia-Drug Information
- DRUGDEX Information System
- American Medical Association Drug Evaluations

Based on this statutory definition, indications are not "medically accepted" if they are supported in peer-reviewed medical literature, but not yet included or approved for inclusion in one of the compendia Therefore, the use of a drug for such indications would not meet the definition of a Part D drug and plans should deny payment.

NON-FDA APPROVED DRUGS

Question 1- Can a drug plan pay for drugs that have not been approved by the FDA?

Answer 1 - Generally no. In order to be considered a Part D drug, a drug generally must be approved by the FDA. However, those limited class of drugs described under section 1927(k)(2)(A)(ii) and (iii) of the Act are also considered Part D drugs. Thus, a drug plan cannot make payment for a non-approved drug as part of its basic benefit unless it is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act. In addition, it cannot provide coverage of such drugs as a supplemental benefit under enhanced coverage.

MEDICAL FOODS

Question 1 - Are medical foods, enteral nutrition or other special dietary formulas included in the Part D benefit?

Answer 1 - In order to be included in the Part D benefit, a product must satisfy the definition of Part D drug and not otherwise be excluded. A Part D drug generally must be regulated by the FDA as a drug, biological or vaccine. While parenteral nutrients are regulated as drugs, medical foods such as enteral nutrients are not. Therefore, these products cannot be covered by Part D plans.

ATTACHMENT III

Websites for Part B Coverage Information

Medicare Claims Processing Manual	http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp?
Medicare Benefit Policy Manual	http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp?
Medicare Coverage Database	http://www.cms.hhs.gov/med/sadexclusion_criteria.asp
Carrier, DMERC, and Fiscal Intermediary contacts by region	http://www.cms.hhs.gov/medlearn/tollnums.asp
Medicare Drug Information Resource	http://www.cms.hhs.gov/providers/drugs/default.asp
Physician Fee Schedule 2005	http://www.cms.hhs.gov/regulations/pfs/2005/1429fc.asp
Hospital Outpatient Prospective Payment System 2005	http://www.cms.hhs.gov/providers/hopps/fr2005.asp
Palmetto GBA	http://www.palmettogba.com
AdminaStar	Http://www.adminastar.com
Health Now New York	http://www.umd/nycpic.com
CIGNA	http://www.cignamedicare.com
National/Local Coverage Determinations	http://www.cms.hhs.gov/mcd/search/asp?

ATTACHMENT IV

Call Center - Toll Free Numbers			
State Served	**Call Center**	**Program**	**Toll-Free Number**
Alabama	BCBS of Alabama Call Center	Provider Services Part A and Part B	866-539-5598
Alabama	Palmetto GBA	Provider Services - Region C DMERC IVR	866-270-4909
Alabama	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Alabama	Palmetto GBA	Provider Services - Region C DMERC	866-238-9650
Alaska	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Alaska	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Alaska	Noridian Government Operations	Provider Enrollment	888-608-8816
Alaska	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Alaska	Noridian Government Operations	Provider Services Part B	877-908-8431
Alaska	Premera Call Center	Provider Services Part A	877-908-8437
Alaska	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
All 50 States	Mutual of Omaha Medicare Call Center	Provider Northeast - Part A	866-580-5945
All 50 States	Mutual of Omaha Medicare Call Center	Provider Southeast - Part A	866-580-5981
All 50 States	Mutual of Omaha Medicare Call Center	Provider Central - Part A	866-580-5984
All 50 States	Mutual of Omaha Medicare Call Center	Provider West - Part A	866-580-5987
All 50 States	Mutual of Omaha Medicare Call Center	Claims Corrections Southeast	866-580-5979
All 50 States	Mutual of Omaha Medicare Call Center	Claims Corrections West	866-580-5980
All 50 States	Mutual of Omaha Medicare Call Center	Claims Corrections Central	866-580-5982
All 50 States	Mutual of Omaha Medicare Call Center	Claims Corrections Northeast	866-580-5985
All 50 States	Mutual of Omaha Medicare Call Center	Systems	866-734-6656
All 50 States	Mutual of Omaha Medicare Call Center	MSP	866-734-1521
All 50 States, Puerto Rico, Virgin Islands, and Guam	Palmetto GBA	Provider Services - National Provider Clearinghouse	866-238-9652
All 50 States, Puerto Rico, Virgin Islands, and Guam	Palmetto GBA	Provider Services - Statistical Analysis DMERC	877-735-1326

All 50 States, Puerto Rico, Virgin Islands, and Guam	Palmetto GBA	Provider MDCN	800-905-2069
All 50 States, Puerto Rico, Virgin Islands, and Guam	Palmetto GBA Railroad Retirement Board Medicare Call Center	Railroad Medicare Part B - National Provider Service Center	877-288-7600
American Samoa	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
American Samoa	Noridian Government Operations	Provider Services Part B	877-908-8431
American Samoa	United Government Services - California Call Center	Provider Inpatient/Outpatient	866-380-4745
American Samoa	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Arizona	BCBS of Arizona Call Center	Provider Services Part A	877-567-3128
Arizona	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Arizona	Noridian Government Operations	Provider Enrollment	888-608-8816
Arizona	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Arizona	Noridian Government Operations	Provider Services Part B	877-908-8431
Arizona	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Arkansas	Arkansas BCBS Call Center	Provider Part A	866-548-0527
Arkansas	Arkansas BCBS Call Center	Provider Carrier Services	877-908-8434
Arkansas	Palmetto GBA	Provider Services - Region C DMERC	866-238-9650
Arkansas	Palmetto GBA	Provider Services - RHHI	877-272-5786
Arkansas	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Arkansas	BCBS Call Center	Provider EMC	866-582-3247
Arkansas	BCBS Call Center	Provider Enrollment Part B	866-582-3251
California	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
California	National Heritage Co.	Provider Services Part B	877-591-1587
California	United Government Services - California Call Center	Provider Inpatient/Outpatient	866-380-4745
California	United Government Services - RHHI	Provider Home Health/Hospice	866-539-5594
California	Veritus Medicare Services	Provider Services Part A	800-560-6170
California (southern)	National Heritage Co.	Provider Inquiry	866-502-9054
California (southern)	National Heritage Co.	Provider Telephone Review	866-539-5597
Colorado	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Colorado	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Colorado	Noridian Government Operations	Provider Enrollment	888-608-8816
Colorado	Noridian Government Operations	Provider EDI, MCS	866-849-7246
Colorado	Noridian Government Operations	Provider Services Part B	877-908-8431

Colorado	Palmetto GBA	Provider Services - Region C DMERC	866-270-4909
Colorado	Palmetto GBA	Provider Services - RHHI	877-272-5786
Colorado	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Colorado	Trailblazer Health Enterprises	Provider Services Part A	888-763-9836
Colorado	Cahaba GBA	Provider EDI	866-839-2441
Connecticut	Associated Hospital Service RHHI Call Center	Provider Services RHHI	877-498-1351
Connecticut	Empire BCBS Call Center	Provider Services Part A	877-567-7205
Connecticut	First Coast Service Options	Provider Services Part B	866-419-9455
Connecticut	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Connecticut	Veritus Medicare Services	Provider Services Part A	800-560-6170
Delaware	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Delaware	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Delaware	Empire BCBS Call Center	Provider Services Part A	877-567-7205
Delaware	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Delaware	Trailblazer Health Enterprises - MD Call Center	Provider Services - Part B	877-391-2610
Delaware	Veritus Medicare Services	Provider Services Part A	800-560-6170
Delaware	Cahaba GBA	Provider EDI	866-839-2441
District of Columbia	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
District of Columbia	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
District of Columbia	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
District of Columbia	CareFirst Call Center	Provider Services Part A	866-488-0545
District of Columbia	Trailblazer Health Enterprises - MD Call Center	Provider Services Part B	877-391-2610
District of Columbia	Cahaba GBA	Provider EDI	866-839-2441
Florida	First Coast Service Options	Provider Services Part A	877-602-8816
Florida	First Coast Service Options	Provider Services Part B IVR	877-847-4992
Florida	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
Florida	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Florida	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Florida	Palmetto GBA RHHI Call Center	Provider Services - RHHI	866-801-5301
Florida	Veritus Medicare Services	Provider Services Part A	800-560-6170
Florida	First Coast Service Options	Provider Service Part B CSR	866-454-9007

Georgia	BCBS of Georgia	Provider EDI	877-567-3095
Georgia	Cahaba Georgia Medicare	Provider MSP	866-582-3243
Georgia	Cahaba Georgia Medicare	Provider Phone Reviews	866-582-3244
Georgia	Cahaba Georgia Medicare	Provider Enrollment	866-582-3246
Georgia	Cahaba Georgia Medicare	Provider Financial	866-582-3249
Georgia	Cahaba Georgia Medicare	Provider EDI Support	866-582-3253
Georgia	Cahaba Georgia Medicare	Provider Inquiries - Part B	877-567-7271
Georgia	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Georgia	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Georgia	Palmetto GBA RHHI Call Center	Provider Services - RHHI	866-801-5301
Georgia	Veritus Medicare Services	Provider Services Part A	800-560-6170
Georgia	BCBS of Georgia	Provider Enrollment	866-305-0028
Guam	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-270-4909
Guam	Noridian Government Operations	Provider Enrollment	888-608-8816
Guam	Noridian Government Operations	Provider Services Part B	877-908-8431
Guam	United Government Services - California Call Center	Provider Inpatient/Part A	866-380-4745
Guam	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Hawaii	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Hawaii	Noridian Government Operations	Provider Enrollment	888-608-8816
Hawaii	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Hawaii	Noridian Government Operations	Provider Services Part B	877-908-8431
Hawaii	United Government Services	Provider Services Part A	866-849-7244
Hawaii	United Government Services - California Call Center	Provider Inpatient/Outpatient	866-380-4745
Hawaii	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Idaho	CIGNA TN	Provider ID Part B	866-502-9051
Idaho	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Idaho	Medicare Northwest Operations	Provider Services Part A	866-801-5302
Idaho	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Illinois	AdminaStar Federal Inc.	Provider Illinois Part A	866-419-9457
Illinois	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Illinois	Palmetto GBA	Provider Benefit Integrity	877-867-4852

Illinois	Palmetto GBA RHHI Call Center	Provider Services - RHHI	866-801-5301
Illinois	Wisconsin Physician Services	Provider EDI Hotline - Part B	877-567-7261
Illinois	Wisconsin Physician Services	Provider IL Appeals - Part B	877-867-3418
Illinois	Wisconsin Physician Services	Provider General Admin.	877-908-4067
Illinois	Wisconsin Physician Services	Provider IL Customer Service - Part B	877-908-9499
Indiana	AdminaStar Federal Inc.	Provider Indiana Part A	866-419-9453
Indiana	AdminaStar Federal Inc.	Provider Indiana Part B	866-250-5665
Indiana	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Indiana	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Indiana	Palmetto GBA Palm Harbor RHHI Call Center	Provider Services - RHHI	866-801-5301
Iowa	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Iowa	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Iowa	Cahaba Government Benefits Administrators (GBA)	Provider Services Part A - Non Home Health and Hospice	877-567-3092
Iowa	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Iowa	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Iowa	Noridian Government Operations	Provider Enrollment	888-608-8816
Iowa	Noridian Government Operations	Provider IA MCS - Part B	866-380-4743
Iowa	Noridian Government Operations	Provider IA Network - Part B	866-502-9057
Iowa	Cahaba GBA	Provider EDI	866-839-2441
Kansas	BCBS of Kansas Call Center	Provider Medicare Review	877-567-7268
Kansas	BCBS of Kansas Call Center	Provider Services Part B	877-567-7270
Kansas	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Kansas	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Kansas	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Kansas	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Kansas	BCBS of Kansas	Provider Records	866-839-2440
Kansas	BCBS of Kansas	Provider Services Part A	866-839-2443
Kansas	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Kentucky	AdminaStar Federal Inc.	Provider Kentucky Part A	866-419-9457
Kentucky	AdminaStar Federal Inc.	Provider Kentucky Part B	866-250-5665
Kentucky	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650

Kentucky	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Kentucky	Palmetto GBA	Provider Services - RHHI	877-272-5786
Kentucky	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Louisiana	BCBS of Arkansas LA Call Center	Provider Services Part B	877-567-7204
Louisiana	TriSpan Health Services Call Center	Provider Services Part A	877-567-3097
Louisiana	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
Louisiana	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Louisiana	Palmetto GBA	Provider Services - RHHI	877-272-5786
Louisiana	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Louisiana	BCBS of Arkansas LA Call Center	Provider Enrollment	866-794-0466
Louisiana	BCBS of Arkansas LA Call Center	Provider MSP Inquiries	866-794-0477
Louisiana	BCBS of Arkansas LA Call Center	Provider EMC Inquiries	866-794-0479
Louisiana	BCBS of Arkansas LA Call Center	Provider Part B Reviews	866-794-0480
Maine	Associated Hospital Service RHHI Call Center	Provider Services RHHI	877-498-1351
Maine	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Maine	Associated Hospital Service	Provider Services Part A	877-567-9250
Maine	National Heritage Co.	Provider Services Part B	877-567-3129
Maine	National Heritage Insurance	Provider Telephone Review	866-361-2923
Maryland	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Maryland	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Maryland	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Maryland	CareFirst Call Center	Provider Services Part A	866-488-0545
Maryland	Trailblazer Health Enterprises - MD Call Center	Provider Services Part B	866-539-5591
Maryland	Veritus Medicare Services	Provider Services Part A	800-560-6170
Maryland	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Massachusetts	Associated Hospital Service Call Center	Provider Services Part A	877-567-9250
Massachusetts	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Massachusetts	National Heritage Co.	Provider Services Part B	877-567-3130
Massachusetts	Veritus Medicare Services	Provider Services Part A	800-560-6170
Michigan	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900

Michigan	United Government Services	Provider Services Part A	866-419-9462
Michigan	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
Michigan	Wisconsin Physician Services	Provider MI Customer Service Part B	877-567-7201
Michigan	Wisconsin Physician Services	Provider EDI Hotline - Part B	877-567-7261
Michigan	Wisconsin Physician Services	Provider MI Appeals - Part B	877-674-5416
Michigan	Wisconsin Physician Services	Provider General Admin. - Part B	877-908-4067
Michigan	Wisconsin Physician Services	Provider General Admin.	877-908-4067
Minnesota	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Minnesota	Noridian Government Operations	Provider Services Part A	866-380-4741
Minnesota	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
Minnesota	Wisconsin Physician Services	Provider EDI Hotline - Part B	877-567-7261
Minnesota	Wisconsin Physician Services	Provider General Admin.	877-908-8475
Minnesota	Wisconsin Physician Services	Provider MN General Admin. - Part B	866-380-4742
Minnesota	Wisconsin Physician Services	Provider Appeals - Part B	866-380-4744
Minnesota	Wisconsin Physician Services	Provider Enrollment - Part B	866-564-0315
Minnesota	Wisconsin Physician Services	Provider MN Customer Service - Part B	877-908-8470
Mississippi	TriSpan Health Services Call Center	Provider Services Part A	877-567-3097
Mississippi	Cahaba Government Benefits Administrators (GBA)	Provider Services Part B	866-419-9454
Mississippi	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
Mississippi	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Mississippi	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Mississippi	Palmetto GBA RHHI Call Center	Provider Services - RHHI	866-801-5301
Missouri	BCBS of Kansas Call Center	Provider Medicare Review	877-567-7268
Missouri	TriSpan Health Services Call Center	Provider Services Part A	877-567-3097
Missouri	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Missouri	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Missouri	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Missouri	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Missouri (eastern)	Missouri Medicare Call Center	Provider Enrollment	866-419-9460

Missouri (eastern)	Missouri Medicare Call Center	Provider Services Part B **IVR**	866-539-5599
Missouri (Western)	BCBS of Kansas	Provider Records	866-839-2440
Missouri (Western)	BCBS of Kansas	Provider Services Part B (Northwest)	866-839-2442
Missouri	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Montana	BCBS of Montana Call Center/Great Falls	Provider Services Part A	877-567-7202
Montana	BCBS of Montana/Helena	Provider Services Part B	877-567-7203
Montana	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Montana	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Montana	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Montana	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Nebraska	BCBS of Kansas Call Center	Provider Services Part B	866-839-2438
Nebraska	BCBS of Nebraska Call Center	Provider Services Part A	877-869-6503
Nebraska	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Nebraska	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Nebraska	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Nebraska	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Nebraska	BCBS of Kansas	Provider Records	866-839-2440
Nebraska	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Nevada	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Nevada	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Nevada	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Nevada	Noridian Government Operations	Provider Services Part B	877-908-8431
Nevada	United Government Services - California Call Center	Provider Inpatient/Outpatient	866-380-4745
Nevada	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
New Hampshire	Associated Hospital Service RHHI Call Center	Provider Services RHHI	877-498-1351
New Hampshire	BCBS of New Hampshire Call Center	Provider Services Part A	866-539-5593
New Hampshire	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
New Hampshire	National Heritage Co.	Provider Services Part B	866-539-5595
New Hampshire	Veritus Medicare Services	Provider Services Part A	800-560-6170
New Hampshire	National Heritage Insurance	Provider Telephone Review	866-361-2923
New Jersey	Empire NJ Call Center	Provider Services Part B **ARU**	877-567-9235
New Jersey	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458

New Jersey	Riverbend Call Center	Provider Services - Part A	877-296-6189
New Jersey	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
New Jersey	Veritus Medicare Services	Provider Services Part A	800-560-6170
New Mexico	BCBS of Arkansas OK/NM Call Center	Provider Enrollment	866-539-5596
New Mexico	BCBS of Arkansas OK/NM Call Center	Provider Services Part B **IVR**	877-567-9230
New Mexico	BCBS of Arkansas OK/NM Call Center	Provider Services Part B	866-280-6520
New Mexico	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
New Mexico	Palmetto GBA	Provider Services - Region C DMERC **CSR**	877-270-4909
New Mexico	Palmetto GBA	Provider Services - RHHI	877-272-5786
New Mexico	Palmetto GBA	Provider Benefit Integrity	877-867-4852
New Mexico	Trailblazer Health Enterprises	Provider Services Part B **IVR**	877-392-9865
New Mexico	Trailblazer Health Enterprises	Provider Services Part A	877-391-2610
New Mexico	Trailblazer Health Enterprises	Provider Services Part A	888-763-9836
New York	Health Now DMERC Call Center	Provider Services Region A DMERC	866-419-9458
New York	Empire BCBS Call Center	Provider Services Part A	877-567-7205
New York	Empire NJ Call Center	Provider Services Part B	877-869-6504
New York	Group Health Inc. Call Center	Provider Services Part B	877-868-7965
New York	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
New York	Veritus Medicare Services	Provider Services Part A	800-560-6170
New York (Western)	Health Now	Provider Services Part B	877-567-7173
North Carolina	Palmetto GBA of North Carolina	Provider Services Part A	877-567-9249
North Carolina	CIGNA NC	Provider NC Part B	866-238-9651
North Carolina	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
North Carolina	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
North Carolina	Palmetto GBA	Provider Services - RHHI	877-272-5786
North Carolina	Palmetto GBA	Provider Benefit Integrity	877-867-4852
North Carolina	Veritus Medicare Services	Provider Services Part A	800-560-6170
North Carolina	Cigna	Provider NC Part B EDI	866-352-1608

North Carolina	Cigna	Provider NC Part B Telephone Reviews	866-352-6695
North Dakota	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
North Dakota	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
North Dakota	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
North Dakota	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
North Dakota	Noridian Government Operations	Provider Enrollment	888-608-8816
North Dakota	Noridian Government Operations	Provider Services Part A	866-380-4741
North Dakota	Noridian Government Operations	Provider EDI, MCS	866-849-7246
North Dakota	Noridian Government Operations	Provider Services Part B	877-908-8431
North Dakota	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Northern Marianna Islands	Noridian Government Operations	Provider Services Part B	877-908-8431
Northern Marianna Islands	Noridian Government Operations	Provider Enrollment	888-608-8816
Northern Marianna Islands	United Government Services - California Call Center	Provider Inpatient/Outpatient	866-380-4745
Northern Marianna Islands	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
Northern Marianna Islands	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Northern Marianna Islands	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Ohio	AdminaStar Cincinnati Call Center	Provider Ohio Part A	866-419-9457
Ohio	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Ohio	Palmetto GBA Call Center	Provider Services Part B	877-567-9232
Ohio	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Ohio	Palmetto GBA RHHI Call Center	Provider Services	866-801-5301
Ohio	Veritus Medicare Services	Provider Services - Part A	800-560-6170
Oklahoma	BCBS of Arkansas OK/NM Call Center	Provider Enrollment	866-539-5596
Oklahoma	BCBS of Arkansas OK/NM Call Center	Provider Services Part B **IVR**	877-567-9230
Oklahoma	BCBS of Arkansas OK/NM Call Center	Provider Services Part B	866-280-6520
Oklahoma	BCBS of Oklahoma	Provider Services Part A	877-567-3094
Oklahoma	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
Oklahoma	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Oklahoma	Palmetto GBA	Provider Services - RHHI	877-272-5786
Oklahoma	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Oregon	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390

Oregon	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
Oregon	Medicare Northwest Call Center	Provider Services Part A	877-567-9234
Oregon	Noridian Government Operations	Provider Enrollment	888-608-8816
Oregon	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Oregon	Noridian Government Operations	Provider Services Part B	877-908-8431
Oregon	United Government Services - RHHI	Provider Home Health/Hospice	866-380-4745
Pennsylvania	Veritus Medicare Services' subcontractor, Blue Cross of North East PA Call Center	Provider Services Part A	866-502-9058
Pennsylvania	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Pennsylvania	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Pennsylvania	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Pennsylvania	Veritus Medicare Services	Provider Services Part A	800-560-6170
Pennsylvania	HGS Administrators PA Call Center	Provider Services Part B	866-488-0548
Pennsylvania	HGS Administrators PA Call Center	Provider Telephone Appeals	866-488-0551
Pennsylvania	HGS Administrators PA Call Center	Provider EDI	866-488-0546
Pennsylvania	HGS Administrators PA Call Center	Provider Enrollment	866-488-0549
Pennsylvania	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Puerto Rico	COSVI-PR Call Center	Provider Services Part A	877-908-8433
Puerto Rico	Palmetto GBA	Provider Services - Region C DMERC **IVR**	866-238-9650
Puerto Rico	Palmetto GBA	Provider Services - Region C DMERC **CSR**	866-270-4909
Puerto Rico	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Puerto Rico	Triple-S Call Center	Provider Services Part B	877-715-1921
Puerto Rico	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
Rhode Island	Associated Hospital Service RHHI Call Center	Provider Services RHHI	877-498-1351
Rhode Island	BCBS of Rhode Island	Provider Services - Part B	866-801-5304
Rhode Island	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458
Rhode Island	BCBS of Rhode Island	Provider Services Part A	866-339-3714
South Carolina	Palmetto GBA	Provider Services Part B	866-238-9654
South Carolina	Palmetto GBA	Provider Services - Region C DMERC	866-238-9650
South Carolina	Palmetto GBA	Provider Services - RHHI	866-801-5301

South Carolina	Palmetto GBA	Provider Benefit Integrity	877-867-4852
South Carolina	Palmetto GBA	Provider Services Part A	877-272-5786
South Dakota	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
South Dakota	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
South Dakota	Cahaba Government Benefits Administrators (GBA)	Provider Services Part A - Non Home Health and Hospice	877-567-3092
South Dakota	CIGNA TN Call Center	Provider Region D DMERC **IVR**	877-320-0390
South Dakota	CIGNA TN Call Center	Provider Region D DMERC **CSR**	866-243-7272
South Dakota	Noridian Government Operations	Provider Enrollment	888-608-8816
South Dakota	Noridian Government Operations	Provider EDI, MCS	866-849-7246
South Dakota	Noridian Government Operations	Provider Services Part B	877-908-8431
South Dakota	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Tennessee	CIGNA TN	Provider TN Part B	866-502-9056
Tennessee	Palmetto GBA	Provider Services - RHHI	877-272-5786
Tennessee	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Tennessee	Riverbend Call Center	Provider Services Part A	877-296-6189
Texas	Palmetto GBA	Provider Services - Region C DMERC	866-238-9650
Texas	Palmetto GBA	Provider Services - RHHI	877-272-5786
Texas	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Texas	Trailblazer Health Enterprises	Provider Services Part B	877-392-9865
Texas	Trailblazer Health Enterprises	Provider Services Part A	888-763-9836
Texas	Trailblazer Health Enterprises - MD Call Center	Provider Services Part B **CSR**	866-211-5708
Utah	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Utah	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Utah	CIGNA TN Call Center	Provider Region D DMERC	877-320-0390
Utah	Regence of Utah	Provider Services Part B	866-539-5600
Utah	Regence of Utah	Provider Review	866-238-9460
Utah	Regence of Utah	Provider Services Part A	877-908-8436
Utah	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Vermont	Associated Hospital Service RHHI Call Center	Provider Services - RHHI	877-498-1351
Vermont	BCBS of New Hampshire Call Center	Provider Services Part A	866-539-5593
Vermont	Health Now DMERC Call Center	Provider Services - Region A DMERC	866-419-9458

Vermont	National Heritage Co.	Provider Services Part B	866-539-5595
Vermont	BCBS of New Hampshire Call Center	Provider Services Part A	866-539-5593
Virgin Islands	COSVI-PR Call Center	Provider Services Part A	877-908-8433
Virgin Islands	Palmetto GBA	Provider Services - Region C DMERC	866-238-9650
Virgin Islands	Palmetto GBA	Provider Benefit Integrity	877-867-4852
Virgin Islands	United Government Services - Milwaukee Call Center	Provider Services - RHHI	877-309-4290
Virginia	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Virginia	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Virginia	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Virginia	Trailblazer Health Enterprises - VA Call Center	Provider Services Part B	866-502-9049
Virginia	United Government Services	Provider Services Part A	877-908-8474
Virginia	Veritus Medicare Services	Provider Services Part A	800-560-6170
Virginia	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Washington	CIGNA TN Call Center	Provider Region D DMERC	877-320-0390
Washington	Noridian Government Operations	Provider Enrollment	888-608-8816
Washington	Noridian Government Operations	Provider EDI, GTE	866-849-7243
Washington	Noridian Government Operations	Provider Services Part B	877-908-8431
Washington	Premera Call Center	Provider Services Part A	877-908-8437
Washington	United Government Services - RHHI	Provider Home Health/Hospice	866-539-5594
West Virginia	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
West Virginia	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
West Virginia	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
West Virginia	Palmetto GBA	Provider Services Part B	877-567-9232
West Virginia	United Government Services	Provider Services Part A	877-908-8474
West Virginia	Veritus Medicare Services	Provider Services Part A	800-560-6170
West Virginia	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441
Wisconsin	Wisconsin Physician Services	Provider EDI Hotline - Part B	877-567-7261
Wisconsin	Wisconsin Physician Services	Provider General Admin. - Part B	877-908-8475
Wisconsin	Wisconsin Physician Services	Provider WI Customer Service - Part B	877-567-7176
Wisconsin	Wisconsin Physician Services	Provider WI Appeals - Part B	877-674-5354
Wisconsin	Wisconsin Physician Services	Provider Enrolment IL/MI Part B	877-908-8476

Wisconsin (Part A RHHI)	United Government Services - Milwaukee Call Center	Provider Services Part A	877-309-4290
Wisconsin	AdminaStar Federal Inc.	Provider Region B DMERC	877-299-7900
Wyoming	BCBS of Wyoming	Provider Services Part A	877-567-3093
Wyoming	Cahaba Government Benefits Administrators (GBA)	Provider Home Health	877-299-4500
Wyoming	Cahaba Government Benefits Administrators (GBA)	Provider Hospice	866-539-5592
Wyoming	CIGNA TN Call Center	Provider Region D DMERC	877-320-0390
Wyoming	Noridian Government Operations	Provider Enrollment	888-608-8816
Wyoming	Noridian Government Operations	Provider EDI, MCS	866-849-7246
Wyoming	Noridian Government Operations	Provider Services Part B	877-908-8431
Wyoming	Cahaba GBA	Provider Home Health/Hospice EDI	866-839-2441

Medicare Parts B/D Coverage Issues

For discussion purposes only – subject to change

This table provides a reference guide for the most frequent B/D coverage determination scenarios facing Part D plans and Part D pharmacy providers. It does not address all potential situations. For more extensive discussion, please refer to the Medicare Part B vs. Part D Coverage Issues document available at:
http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf

Part B Coverage Categories	Part B Coverage Description	Retail and Home Infusion Pharmacy Setting B/D Coverage	LTC Pharmacy Setting B/D Coverage	Comments	Written Prescription Indicators to Highlight B/D Coverage
Durable Medical Equipment (DME) Supply Drugs **NOTE: Only available for beneficiaries residing in their "home"**[1]	Drugs that require administration via covered DME (e.g. nebulizer drugs, drugs "requiring" a pump for infusion, and insulin via infusion pump)[2]	**Part B**	**Part D** Because most LTC facilities are not considered a beneficiary's "home"[3]		**Part B**: "*To be administered in the home setting with DME (i.e.,. nebulizer or infusion pump)*" **Part D**: "*To be administered in a LTC facility*"[4]

[1] In addition to a hospital, a SNF or a distinct part SNF, the following facility or distinct parts of facilities cannot be considered a home for purposes of receiving the Medicare Part B DME benefit:

- A nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF)
- A Medicaid-only NF that primarily furnishes skilled care;
- A non-participating nursing home (i.e. neither Medicare nor Medicaid) that provides primarily skilled care; and
- A distinct part of a facility that primarily furnishes skilled care.

[2] The DMERCs do a medically necessity determination with regard to whether a nebulizer or infusion pump is medically necessary for a specific drug/condition.

[3] If a facility does not meet the criteria in footnote 1, it would be considered a home, and Part B could cover the drugs.

[4] Prescriptions for inhalation drugs to be used with a non-covered nebulizer or a hand held insufflator would also be covered under Part D.

Medicare Parts B/D Coverage Issues

For discussion purposes only – subject to change

Part B Coverage Categories	Part B Coverage Description	Retail and Home Infusion Pharmacy Setting B/D Coverage	LTC Pharmacy Setting B/D Coverage	Comments	Written Prescription Indicators to Highlight B/D Coverage
Drugs furnished "incident to" a physician service	Injectable/ Intravenous drugs 1) administered "incident to" a physician service and 2) considered by Part B carrier as "not usually self-administered".	**Part D** Because by definition a pharmacy cannot provide a drug "incident to" a physician's service (Only a physician office, or where applicable a CAP vendor, would bill Part B for "incident to" drugs).	**Part D** Because by definition a pharmacy cannot provide a drug "incident to" a physician's service (Only a physician office, or where applicable a CAP vendor, would bill Part B for "incident to" drugs).[5]	Part D plans should not implement pharmacy edits to determine B vs. D coverage for injectable/IV drugs only covered under Part B when furnished "incident to" a physician service.	
Immunosuppressant Drugs	Drugs used in immunosuppressive therapy for beneficiaries that received transplant from Medicare approved facility and were entitled to Medicare Part A at time of transplant (i.e. "Medicare Covered Transplant").	**B or D:** **Part B** for Medicare Covered Transplant **Part D** for all other situations	**B or D:** **Part B** for Medicare Covered Transplant **Part D** for all other situations	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.	**Part B**: "*For Medicare-covered transplant*" **Part D**: "*For rheumatoid arthritis* (or other non-transplant use)" or "*Not for Medicare-covered transplant*"

[5] For a LTC resident, if a physician furnishes the drug from the physician's own stock, administers or directly supervises the administration of the drug, and bills for the drug, then the drug would be considered "incident to" and covered under Part B

Medicare Parts B/D Coverage Issues

For discussion purposes only – subject to change

Part B Coverage Categories	Part B Coverage Description	Retail and Home Infusion Pharmacy Setting B/D Coverage	LTC Pharmacy Setting B/D Coverage	Comments	Written Prescription Indicators to Highlight B/D Coverage
Oral Anti-Cancer Drugs	Oral drugs used for cancer treatment that contain same active ingredient (or pro-drug) as injectable dosage forms that would be covered as 1) not usually self administered and 2) provided incident to a physician's service	**B or D:** **Part B** for cancer treatment **Part D** for all other indications	**B or D:** **Part B** for cancer treatment **Part D** for all other indications	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.	**Part B**: "*For the treatment of _____ cancer*" **Part D**: "*For rheumatoid arthritis* (or other non-cancer use)" or "*Not for the treatment of cancer*"
Oral Anti-emetic Drugs	Oral anti-emetic drugs used as full therapeutic replacement for IV anti-emetic drugs within 48 hrs of chemo	**B or D:** **Part B** within 48 hrs of chemo **Part D** all other situations	**B or D:** **Part B** within 48 hrs of chemo **Part D** all other situations	Participating Part B pharmacies must bill the DMERC in their region when these drugs are covered under Part B.	**Part B**: "*To be used within 48 hours of chemotherapy*"[6] **Part D**: "*To be used beyond 48 hours of chemotherapy*" or "*For _____* (any non-chemotherapy-associated use)"[7]

[6] "*To be used within 24 hours of chemotherapy*" for granisetron and dolasetron.

[7] Consider separate prescriptions for chemotherapy-related anti-emetics if administration will exceed Part B coverage limits

Medicare Parts B/D Coverage Issues

For discussion purposes only – subject to change

Part B Coverage Categories	Part B Coverage Description	Retail and Home Infusion Pharmacy Setting B/D Coverage	LTC Pharmacy Setting B/D Coverage	Comments	Written Prescription Indicators to Highlight B/D Coverage
Erythropoietin (EPO)	Treatment of anemia for persons with chronic renal failure who are undergoing dialysis when given in the dialysis center or when given "incident to physician's service" for other approved uses	**Part D**	**Part D**	For Part B coverage of EPO for ESRD patients undergoing dialysis, the claim must be submitted by the ESRD facility and we would thus not anticipate prescriptions in the retail setting for this covered use	**Part D**: "*For the treatment of* _____ "
Prophylactic Vaccines (Influenza, pneumococcal, and hepatitis B)	Influenza, Pneumococcal, and hepatitis B (for intermediate to high risk beneficiaries).	**B or D:** **Part B** for Influenza, pneumococcal, & hepatitis B (for intermediate to high risk) **Part D** for all other hepatitis B vaccinations	**B or D:** **Part B** for influenza, pneumococcal, & hepatitis B (for intermediate to high risk) **Part D** for all other hepatitis B vaccinations		**Part B** (hepatitis B): "*For high or intermediate risk*" **Part D** (hepatitis B): "*For lower risk*" Note: Influenza and pneumococcal vaccines are not covered under Part D

Medicare Parts B/D Coverage Issues

For discussion purposes only – subject to change

Part B Coverage Categories	Part B Coverage Description	Retail and Home Infusion Pharmacy Setting B/D Coverage	LTC Pharmacy Setting B/D Coverage	Comments	Written Prescription Indicators to Highlight B/D Coverage
Other Prophylactic Vaccines		**Part D,** except as described in the comments	**Part D,** except as described in the comments	All other prophylactic vaccines generally would be covered under Part D. The exception to this is vaccines given to treat an injury or as a result of direct exposure to a disease or condition. In those circumstances, the vaccine is covered under Part B when provided incident to a physician service.	**N/A**
Parenteral Nutrition	Prosthetic benefit for individuals with "permanent" dysfunction of the digestive tract. If medical record, including the judgment or the attending physician, indicates that the impairment will be long and indefinite duration, the test of permanence is met.	**B or D:** **Part B** if "permanent" dysfunction of digestive tract **Part D** for all other situations	**B or D:** **Part B** if "permanent" dysfunction of digestive tract **Part D** for all other situations	Part D does not pay for the equipment/supplies and professional services associated with the provision of parenteral nutrition or other Part D covered infusion therapy.	**Part B**: "*For permanent dysfunction of digestive tract*" **Part D**: "*For* _____ (other uses)"

Appendix A.

Examples of Drugs that may Require an External Infusion Pump for Administration

ACYCLOVIR
AMPHOTERICIN B
BLEOMYCIN
CLADRIBINE
CYTARABINE
DEFEROXAMINE MESYLATE
DOBUTAMINE
DOPAMINE
DOXORUBICIN
EPOPROSTENOL
FENTANYL
FLOXURIDINE
FLUOROURACIL
FOSCARNET
GALLIUM NITRATE
GANCICLOVIR
HYDROMORPHONE
INSULIN
MEPERIDINE
MILRINONE
TREPROSTINIL
VINBLASTINE
ZICONOTIDE

Appendix D

Formulary Key Drug Types Exempt From Drug List Review Check

Antiarhythmics (Other)
Osmotic Diuretics
Osmotic Agents, Ophthalmic
Parathyroid/Metabolic Bone Disease Agents (Other)
Retinal Agents, Ophthalmic

Appendix E

The most commonly prescribed drug classes for the general Medicare and the dually eligible population

Top Drug Classes

ACE inhibitors	Macrolides
Alpha-2 adrenergic agonists	Nitrates
Alpha blockers	Non-opioid analgesics
Angiotensin receptor blockers	Non-sedating antihistamines
Anticholinergic bronchodilators	Ophthalmic prostaglandins
Anticoagulants	Opioid analgesics
Antidyskinetics	Penicillins
Antiemetics	Platelet aggregation inhibitors
Antigout agents	Potassium sparing diuretics
Atypical antipsychotics	Potassium supplements
Beta-blockers	Proton pump inhibitors
Biguanides	Quinolones
Bisphosphonates	Sedatives
Calcium channel blockers	Selective estrogen receptor modifiers
Cardiac inotropes	Serotonin modifiers
Cephalosporins	Short-acting and intermediate-acting insulin mixtures
Cholesterol absorption inhibitors	Short-acting beta agonists
Cholinesterase inhibitors	Short-acting insulins
Corticosteroids	Skeletal muscle relaxants
Cox-2 inhibitors	Sodium channel inhibitors
Estrogens	SSRIs
GABA agents	Statins
Inhaled corticosteroid	Sulfonylureas
Intermediate-acting insulins	Thiazide diuretics
Intranasal corticosteroids	Thiazolidinediones
Laxatives	Thyroid replacements
Leukotriene modifiers	Tricyclic antidepressants
Long-acting beta agonists	Urinary Antispasmodics
Loop diuretics	