

HOME INTRAVENOUS DRUG THERAPY: PROPOSED REGULATIONS UNDER THE MEDICARE CATASTROPHIC COVERAGE ACT

The Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360) included a new Medicare benefit that would have covered home intravenous drug therapy. The act, and the benefit, were repealed the following year. Shortly before the repeal, however, the Health Care Financing Administration (HCFA) had published proposed regulations to implement this new benefit. Although the proposed rules were never made final, they generated considerable comment from the industry, and they represent a potential baseline against which any future related policies can be compared.

The remainder of this appendix presents excerpts from the *Federal Register* that relate to coverage and payment for home intravenous drug therapy. Exerpts are ordered as follows:

- list of covered home intravenous drugs (54 F.R. 37239, Sept. 7, 1989);
- payment for covered outpatient drugs (54 F.R. 37208, Sept. 7, 1989);
- coverage of home intravenous drug therapy services (54 F.R. 37422, Sept. 8, 1989);
- payment for home intravenous drug therapy services (54 F.R. 46938, Nov. 8, 1989); and
- conditions of participation for home intravenous drug therapy providers (54 F.R. 37220, Sept. 7, 1989).

Specific relevant sections and paragraphs are excerpted verbatim (including abbreviations), but sections omitted are not explicitly indicated. Headings and some sections have been reformatted for publication purposes in this report.

List of Covered Home IV Drugs (54 F.R. 37239)

This notice sets forth a list of intravenous drugs that we [HCFA] propose to cover on the basis that they can be safely and effectively administered in the home. The notice would implement section 1861(t)(4) of the Social Security Act as added by section 202(a) of the Medicare Catastrophic Coverage act of 1988.

Home IV Coverage

Section 202(a) of Pub. L. [Public Law] 100-360 amended sections 1861(s)(2)(J) and (t) of the Act to provide general coverage for outpatient prescription drugs under Part B and to authorize Part B coverage of home IV drugs. In addition, section 203 of Pub. L. 100-360 added sections 1861(jj), 1834(d) and 1835(a)(2)(G) to the Act and amended other related sections to authorize

coverage of home IV therapy services. For purposes of this new home IV benefit, under new section 1861(t)(4)(B) of the Act, we are required to publish, by January 1, 1990 and periodically thereafter, a list of covered home IV drugs, and their indications, that can be safely and effectively administered in the home.

It is this list of drugs that we are addressing in this proposed notice. Proposed rules setting forth regulations to implement the various other provisions of Pub. L. 100-360 dealing with the outpatient prescription and home IV drug benefits will be published in separate documents as follows:

- Overall coverage of outpatient prescription drugs (including drugs used in immunosuppressive therapy and home IV drugs).
- Payment methodology for covered outpatient prescription drugs (which will apply also to covered home IV drugs).
- Coverage of home IV drug therapy services.
- Conditions of participation for home TV drug therapy providers.
- Fee schedule for home IV drug therapy services.
- Deductible and coinsurance amounts and the Part B cap on out-of-pocket expenses.
- Participating pharmacies.
- Drug bill processors.
- Coverage of catastrophic Part B expenses, outpatient drug expenses, and respite care benefits for beneficiaries enrolled in pre-pay health plans, such as health maintenance organizations.

The statute provides specific definitions of “covered outpatient prescription drugs” and of what constitutes “covered home IV drugs. In order to be a covered home IV drug, the drug must first qualify as a covered outpatient prescription drug as described below.

Section 202(a) of Pub. L. 100-360 amended sections 1861(s)(2)(J) and (t) of the Act by establishing the following definition of a “covered outpatient drug,” which includes drugs, biological products, and insulin.

Drugs-A drug that may be dispensed only upon prescription and that meets one of the following requirements:

- The drug is approved for safety and effectiveness as a prescription drug under sections 505 or 507 of the FFDCA [Federal Food, Drug, and Cosmetic Act], or approved under section 505(j) of the FFDCA.

- . The drug was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 (October 10, 1962) or it is identical, similar or related to such a drug, as defined by 21 CFR 310.6(b)(1). Nevertheless, such a drug will not be covered if the Secretary has made a final determination that it is a “new drug” and has not been approved under sections 505 or 507 of the FDCA, or if it is subject to certain actions brought by the Secretary to enforce provisions of sections 502(f), or 505(a) of the FDCA (21 U.S.C. 352(f), or 355(a)).
- . The drug is described in section 107(c)(3) of the Drug Amendments of 1962 and is one for which the Secretary has determined there is compelling justification for its medical need, or it is identical, similar, or related to such a drug. Also, the drug must be one for which the Secretary has not issued a notice to withdraw approval for marketing, because the Secretary has determined that the drug is less than effective for all conditions of use represented, recommended, or suggested on its labeling. These are the “DESI” [Drug Efficacy Study Implementation] drugs.

Biological products—A biological product is considered a “covered outpatient drug” if it is one that may be dispensed only upon prescription, is licensed under section 351 of the PHS [Public Health Service] Act (42 U.S.C. 262), and is produced at an establishment licensed under that Act to produce that product.

Insulin—Insulin is covered if it is certified under section 506 of the FDCA (21 U.S.C. 356) for the strength, quality, and purity necessary to ensure adequate safety and efficacy of use. In accordance with section 1861(t)(2)(C) of the Act, as amended by Pub. L. 100-360, insulin would be considered a “covered outpatient drug” whether or not it is dispensed under a prescription.

In addition, section 202(a)(2)(C) of Pub. L. 100-360 added sections 1861(t)(4)(A) and (B) to the Act to define “covered home IV drugs” as covered outpatient drugs that are intravenously administered to individuals in places of residence that are used as the individuals’ homes. The definition includes:

- Antibiotic drugs unless the Secretary has determined, for a specific drug or for the indication for which it is applied, that the drug cannot generally be administered safely and effectively in a home setting; and
- Drugs that are not antibiotics, but only if the Secretary has determined that for a specific drug and the indications for which the drug is being applied that it can generally be administered safely and effectively in a home setting.

Process Followed in Compiling the Drug List

Description of **the** Process—As noted above, section 202(a)(2)(C) of Pub.L. 100-360 added section 1861(t)(4)(B) to the Act to require us to develop a list of covered home IV drugs by January 1, 1990. These drugs must meet definitions of a “covered outpatient drug” set forth in new sections 1861(t)(2) and (2) or the Act and of a “covered home IV drug” set forth in new section 1861(t)(4)(A) of the Act.

Our task with respect to putting together a proposed list of covered home IV drugs has been twofold. First, we had to compile a list of IV drugs (both antibiotics and non-antibiotics) and their indications. Second, in accordance with section 1861(t)(4) of the Act, we had to identify from that list those IV drugs that are safe and effective for use in the home. In accordance with section 1861(t)(4)(A)(ii) of the Act, our rules for including antibiotics and non-antibiotics differed. We obtained information about IV drugs based on the following categories:

- . Antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home.
- . Non-antibiotic IV drugs, and indications for which each drug is applied, that can generally be safely and effectively administered in the home. We separated this category into the following groups:
 - Anti-infectives (other than antibiotics);
 - Hydration therapy;
 - Pain management drugs;
 - Antineoplastic drugs; and
 - Other drugs.

In determining which drugs may be administered intravenously, we obtained the following lists from the FDA:

- **All IV drugs that are currently approved by the FDA for marketing.**
- **DESI drugs, [and]**
- **“Compliance Report for DESI-2,” also referred to as the “B List” of unapproved drugs that are currently marketed.**

The drugs that we considered for our proposed list had to meet the statutory definition of “covered outpatient drug” and can be found on one of these FDA generated lists. Before we reviewed a specific drug for possible inclusion as a “covered home IV drug,” the drug had to meet this initial requirement, as set forth in section 1861(t) of the Act.

In listing the drugs, we decided to place together in one list all those drugs, both antibiotics and non-antibiotics, that we initially propose as being covered. We believe setting forth a comprehensive list of covered drugs for

purposes of rulemaking will make it easier for the public to direct their comments appropriately to a specifically named drug or indication, as opposed to our soliciting comments on those antibiotics and their indications that we propose not to cover. As discussed below, we encountered special problems with unlabeled indications for antibiotics in this regard. Therefore, [Table C-1] to this notice contains a list of drugs and indications that we propose to cover. [Table C-2] contains a list of antibiotics and indications that we propose not to cover.

We want to emphasize that we do not have the discretion under the home IV drug benefit to pay for a drug or an indication that is not on the final list. Section 1861(t)(4)(A) of the Act, as added by section 202(a) of Pub. L. 100-360, limits coverage of home IV drugs to those drugs that the Secretary has determined are safe and effective for use in the home. Any drug or indication not addressed on the final list to be published after we consider and evaluate public comments on the attached proposed list, or any drug or indication not included in a subsequent update, would not meet this requirement and payment would not be made for that drug or indication.

To obtain advice in determining whether an IV drug should be included in our proposed list of IV drugs as being safe and effective for use in the home, we contacted the following organizations:

- . The U.S. Pharmacopoeia (UPS).
- . The American Society of Hospital Pharmacists (ASHP).
- . The American Medical Association (AMA).
- Various home IV providers (recognized in the field of home IV therapy).
- The pharmaceutical Manufacturers Association.
- Various drug manufacturers.

We requested that these sources submit a list of IV drugs that, in their opinion, could generally be safely and effectively administered in the home, and, in addition, any other information they thought pertinent. Although all of the organizations we contacted did not respond with recommendations about drugs suitable for home use, we did receive specific recommendations based on reviews by advisory panels, medical and clinical evidence to support inclusion of certain drugs, lists of IV drugs that are currently being administered in the home setting, and recommendations for exclusions.

In addition, we contacted the publishers of the following compendia:

- United States Pharmacopoeia Dispensing Information, Volume 1 (Drug Information for the Health Care Professional)(USP DI);
- American Medical Association's Drug Evaluations (AMADE); and

- . American Hospital Formulary Service Drug Information (AHFS DI).

Based on the information we received from all of these sources, we constructed an initial list of IV drugs that we considered for inclusion on the proposed list as being safe and effective for home use. (At this point, the list included certain antineoplastic drugs but did not include 12 of the antibiotic drugs that were included on the master list of IV drugs submitted to us by the FDA. For reasons discussed below, neither of these groups of drugs is included in [table C-1].) We then obtained from the FDA the labeled indications for these drugs.

For the purpose of determining unlabeled uses of approved drugs, we relied on the information provided by the three compendia and the suggestions of the various home IV providers.

Having put together the list of IV drugs and indications, we then submitted it to health care professionals recommended to us by the Intravenous Nurses Society and the AMA [American Medical Association]. We requested that these individuals examine the list from a clinical perspective and we received several clinical recommendations.

As noted earlier, our rules for including antibiotic and non-antibiotic drugs on the proposed list have differed. The law requires the Secretary to cover all antibiotic drugs unless the Secretary makes the determination that a specific antibiotic cannot generally be administered safely and effectively in the home. The list of IV drugs we initially obtained from the FDA included identification of all IV antibiotic drugs that are currently available on the market. Of those antibiotic drugs, there were 12 antibiotics that we are proposing as not generally being safe and effective for use in the home.

It is our understanding that the following factors may prevent these 12 drugs that we propose for exclusion from being safe or effective when administered in the home setting:

- . Potential serious or life-threatening side effects;
- Stringent monitoring requirements that could not effectively be performed in the home setting; and
- . Stability limitations.

We list these 12 antibiotics below and specifically solicit comments and information about these drugs and their indications that might be relevant to a final determination about their suitability for use in the home. The drugs are:

1. Chloramphenicol sodium succinate
2. Colistimethate sodium
3. Doxycycline hyclate
4. Erythromycin gluceptate
5. Erythromycin lactobionate

Table C-I—Proposed List of Covered Home IV Drugs and Indications

Approved drug/Approved conditions	Approved drug/Approved conditions
Antibiotics	Skin and skin structure infections
Amdinocillin	Urinary tract infections, bacterial
Urinary tract infections, bacterial	Cefotaxime sodium
Amikacin sulfate	Bone and joint infections
Bone and joint infections	Endocarditis, bacterial
Endocarditis, bacterial	Genitourinary tract infections
Genitourinary tract infections	Skin and skin structure infections
Skin and soft-tissue infection	Urinary tract infections, bacterial
Urinary tract infections, bacterial	Cefotetan disodium
Ampicillin sodium	Bone and joint infections
Arthritis, gonococcal	Endocarditis, bacterial
Bone and joint infections	Genitourinary tract infections
Endocarditis, bacterial	Skin and skin structure infections
Enterocolitis, "Shigella"	Urinary tract infections, bacterial
Genitourinary tract infections	Cefoxitin sodium
Gonorrhea	Bone and joint infections
"Hemophilus" infections	Endocarditis, bacterial
Listeriosis	Genitourinary tract infections
Paratyphoid fever	Skin and skin structure infections
Skin and soft-tissue infections	Urinary tract infections, bacterial
Urethritis, gonococcal	Ceftazidime
Ampicillin sodium and sulbactam sodium	Bone and joint infections
Bone and joint infections	Endocarditis, bacterial
Endocarditis, bacterial	Genitourinary tract infections
Genitourinary tract injections	Skin and skin structure infections
Skin and skin structure infections	Urinary tract infections, bacterial
Azlocillin sodium	Ceftizoxime sodium
Bone and joint infections	Bone and joint infections
Endocarditis, bacterial	Endocarditis, bacterial
Skin and skin structure infections	Genitourinary tract infections
Urinary tract infections, bacterial	Skin and skin structure infections
Aztreonam	Urinary tract infections, bacterial
Bone and joint infections	Ceftriaxone sodium
Endocarditis, bacterial	Bone and joint infections
Genitourinary tract infections	Endocarditis, bacterial
Skin and skin structure infections	Genitourinary tract infections
Urinary tract infections, bacterial	Skin and skin structure infections
Carbenicillin Disodium	Urinary tract infections, bacterial
Genitourinary tract infections	Lyme Disease, joint and Central Nervous System (CNS)
Skin and soft-tissue infections	Cefuroxime sodium
Urinary tract infections, bacterial	Bone and joint infections
Cafamandole nafate	Endocarditis, bacterial
Bone and joint infections	Genitourinary tract infections
Endocarditis, bacterial	Skin and skin structure infections
Genitourinary tract infections	Urinary tract infections, bacterial
Skin and skin structure infections	Gonorrhea
Urinary tract infections, bacterial	Cephalothin sodium
Cefonicid sodium	Bone and joint infections
Bone and joint infections	Endocarditis, bacterial
Endocarditis, bacterial	Genitourinary tract infections
Genitourinary tract infections	Skin and soft tissue infections
Skin and skin structure infections	Urinary tract infections, bacterial
Urinary tract infections, bacterial	Cephapirin sodium
Cefoperazone sodium	Bone and joint infections
Bone and joint infections	Endocarditis, bacterial
Endocarditis, bacterial	Genitourinary tract infections
Genitourinary tract infections	Skin and skin structure infections
Skin and skin structure infections	Urinary tract infections, bacterial
Urinary tract infections, bacterial	Cephadrine
Ceforanide	Bone and joint infections
Bone and joint infections	Endocarditis, bacterial
Endocarditis, bacterial	Genitourinary tract infections
Genitourinary tract infections	Skin and skin structure infections
	Urinary tract infections, bacterial

Table C-I—Proposed List of Covered Home IV Drugs and Indications-Continued

Approved drug/Approved renditions	Approved drug/Approved conditions
Clindamycin phosphate	Genitourinary tract infections
Bone and joint infections	Skin and skin structure infections
Genitourinary tract infections	Urinary tract infections, bacterial
Skin and soft tissue infections	Urethritis, gonococcal
Gentamicin sulfate	Ticarcillin disodium
Bone and joint infections	Bone and joint infections
Endocarditis, bacterial	Endocarditis, bacterial
Genitourinary tract infections	Genitourinary tract infections
Skin and skin structure infections	Skin and soft tissue infections
Urinary tract infections, bacterial	Urinary tract infections, bacterial
Listeriosis	Ticarcillin disodium and
Imipenem and Cilastatin Sodium	clavulanate potassium
Bone and joint infections	Bone and joint infections
Genitourinary tract infections	Endocarditis, bacterial
Skin and skin structure infections	Genitourinary tract infections
Urinary tract infections, bacterial	Skin and skin structure infections
Methicillin sodium	Urinary tract infections, bacterial
Endocarditis, bacterial	Tobramycin sulfate
Skin and soft tissue infections	Bone and joint infections
Mezlocillin sodium	Endocarditis, bacterial
Bone and joint infections	Genitourinary tract infections
Endocarditis, bacterial	Skin and skin structure infections
Genitourinary tract infections	Urinary tract infections, bacterial
Skin and skin structure infections	Listenosis
Urinary tract infections, bacterial	Vancomycin hydrochloride
Miconazole	Bone and joint infections
Candidiasis, disseminated	Endocarditis, bacterial
Candidiasis, mucocutaneous, chronic	
Petriellidiosis	Non-antibiotic drugs
Urinary bladder infections, fungal	<i>Anti-in fectives (other than antibiotics)</i>
Nafcillin sodium	Acyclovir sodium
Endocarditis, bacterial	Herpes zoster
Skin and soft tissue infections	Herpes simplex
Netilmicin Sulfate	Pentamidine isethionate
Bone and joint infections	Pneumonia, "Pneumocystis carinii"
Endocarditis, bacterial	Leishmaniasis, visceral
Genitourinary tract infections	Trypanosomiasis, African
Skin and skin structure infections	Sulfamethoxazole and trimethoprim
Urinary tract infections, bacterial	Bone and joint infections
Oxacillin sodium	Chancroid
Endocarditis, bacterial	Chlamydial infections
Skin and soft tissue infections	Enterocolitis "Shigella"
Penicillin G Potassium	Genitourinary tract infections
Arthritis, gonococcal	Gonorrhea
Diphtheria, prophylaxis	"Hemophils" infections
Endocarditis, bacterial	Lymphogranuloma venereum
Genitourinary tract infections	Paratyphoid fever
Gingivostomatitis, necrotizing	Pneumonia, "Pneumocystis carinii"
ulcerative	Rheumatic fever
Listeriosis	Urinary tract infections, bacterial
Lyme disease, joint and CNS	
Syphilis	Hydration Therapy
Penicillin G sodium	Intravenous solutions
Arthritis, gonococcal	1. Dextrose in water solutions
Diphtheria prophylaxis	2. Sodium chloride solutions
Endocarditis, bacterial	3. Dextrose/sodium chloride solutions
Genitourinary tract infections	4. Premixed potassium chloride solutions up to concentrations of
Gingivostomatitis, necrotizing	40 mEq/Lip
ulcerative	
Listenosis	The following limitations apply for all of the above solutions:
Lyme disease, joint and CNS	a. concentration of dextrose in any solution is not to exceed
Syphilis	10%.
Piperacillin sodium	b. concentration of sodium chloride in any solution is not to
Bone and joint infections	exceed 0.9%0.
Endocarditis, bacterial	

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Table C-I—Proposed List of Covered Home IV Drugs and Indications-Continued

Approved drug/Approved conditions	Approved drug/Approved conditions
<p>5. premixed electrolyte solutions, containing any combination of the following electrolytes in their various salt forms, which are not intended for parenteral nutrition:</p> <p>Sodium</p> <p>Potassium</p> <p>Calcium</p> <p>Magnesium</p> <p>Chloride</p> <p>Phosphate</p> <p>The caloric content of these solutions is limited to 340 calories.</p> <p>Electrolytes</p> <ol style="list-style-type: none"> 1. Calcium chloride 2. Calcium gluconate 3. Calcium gluceptate 4. Magnesium chloride 5. Magnesium sulfate 6. Potassium acetate 7. Potassium chloride 8. Potassium phosphate 9. Sodium acetate 10. Sodium bicarbonate 11. Sodium chloride 12. Sodium phosphate <p>The indications for drugs in this category are less specific than for other drugs. After referring to various clinical tests, we have determined that water depletion, and combined water and electrolyte depletion, can be the result of many disease and non-disease states, including but not limited to the following:</p> <p>Extrarenal losses</p> <ol style="list-style-type: none"> 1. Gastrointestinal (vomiting, diarrhea, ostomy drainage) 2. Skin losses (sweating, burns) 3. Lung losses (bronchorrhea) <p>Renal losses</p> <ol style="list-style-type: none"> 1. Renal disease (chronic renal failure, diuretic phase of acute renal failure) 2. Diuretic excess 3. Osmotic diuresis (diabetic glycosuria) 4. Mineralcorticoid deficiency (Addison's disease, hypoadosteronism) <p>There may be other instances when a patient needs hydration therapy. Patients taking antineoplastic drugs must often be hydrated to increase urine output to insure the timely excretion of the drug because of its toxic side effects.</p> <p>Pain Management Drugs</p> <p>Indication: for treatment of chronic intractable pain.</p> <p>Butorphanol tartrate</p> <p>Hydromorphone hydrochloride</p> <p>Meperidine hydrochloride</p> <p>Morphine sulfate</p> <p>Other</p> <p>Aminophylline</p> <p>Asthma, bronchila</p> <p>Bumetanide</p> <p>Edema</p> <p>Cimetidine hydrochloride</p> <p>Adenoma, multiple endocrine</p> <p>Bleeding, upper gastrointestinal</p> <p>Hypersecretory conditions, gastric</p> <p>Mastocytosis, systemic</p> <p>Pancreatic insufficiency</p> <p>Reflux, gastroesophageal</p> <p>Stress-related mucosal damage</p>	<p>Ulcer, duodenal</p> <p>Ulcer, gastric</p> <p>Zollinger-Ellison syndrome</p> <p>Deferoxamine mesylate</p> <p>Toxicity, iron chronic</p> <p>Toxicity, aluminum</p> <p>Dexamethasone sodium phosphate</p> <p>Adrenocortical insufficiency, chronic primary (Addison's)</p> <p>Adrenocortical insufficiency, secondary</p> <p>Adrenogenital syndrome (adrenal hyperplasia, congenital)</p> <p>Anemia, hemolytic, acquired (autoimmune)</p> <p>Anemia, hypoplastic, congenital (erythroid)</p> <p>Anemia, red blood cell (erythroblastopenia)</p> <p>Arthritis, psoriatic</p> <p>Arthritis, rheumatoid</p> <p>Bowel disease, inflammatory, including colitis, ulcerative</p> <p>Bronchitis, asthmatic, acute or chronic</p> <p>Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)</p> <p>Carcinoma, breast</p> <p>Carcinoma, prostatic</p> <p>Connective tissue disease, mixed</p> <p>Dermatitis, exfoliative</p> <p>Dermatitis herpetiformis bullous</p> <p>Dermatitis, seborrheic, severe</p> <p>Dermatomyositis, systemic</p> <p>Dermatoses, inflammatory, severe (Stevens-Johnson syndrome)</p> <p>Fever, due to malignancy</p> <p>Gouty arthritis, acute</p> <p>Hemolysis</p> <p>Hypercalcemia associated with neoplasms (or sarcoidosis)</p> <p>Increased cranial pressure due to malignancy</p> <p>Leukemia acute or chronic</p> <p>Lupus erythematosus, systemic</p> <p>Lymphomas, Hodgkins, or non-Hodgkins</p> <p>Multiple myeloma</p> <p>Mycosis fungoides</p> <p>Nausea and vomiting, cancer-chemotherapy induced</p> <p>Penphigoid</p> <p>Pemphigus</p> <p>Polychondritis, relapsing</p> <p>Polymyalgia, rheumatic</p> <p>Polyps, nasal</p> <p>Pulmonary disease, chronic obstructive (not controlled with theophylline and beta-adrenergic agonists)</p> <p>Reiter's disease</p> <p>Rheumatic fever</p> <p>Rhinitis, allergic, perennial, or seasonal, severe</p> <p>Thrombocytopenia secondary in adults</p> <p>Thrombocytopenia purpura, idiopathic, in adults</p> <p>Trichinosis</p> <p>Diphenhydramine hydrochloride</p> <p>Nausea and vomiting</p> <p>Famotidine</p> <p>Adenoma, multiple endocrine</p> <p>Bleeding, upper gastrointestinal</p> <p>Hypersecretory conditions, gastric</p> <p>Mastocytosis, systemic</p> <p>Pancreatic insufficiency</p> <p>Reflux, gastroesophageal</p> <p>Stress-related mucosal damage</p> <p>Ulcer, duodenal</p> <p>Ulcer, gastric</p> <p>Zollinger-Ellison syndrome</p>

Table C-I—Proposed List of Covered Home IV Drugs and indications-Continued

Approved drug/Approved conditions	Approved drug/Approved conditions
Furosemide	Arthritis, psoriatic
Edema	Arthritis, rheumatoid
Heparin Calcium	Bowel disease, inflammatory, including colitis, ulcerative
Heparin sodium	Bronchitis, asthmatic, acute or chronic
Thromboembolism	Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)
Hydrocortisone sodium phosphate	Carcinoma, breast
Hydrocortisone sodium succinate	Carcinoma, prostatic
Adrenocortical insufficiency, chronic primary (Addison's)	Connective tissue disease, mixed
Adrenocortical insufficiency, secondary	Dermatitis, exfoliative
Adrenogenital syndrome (adrenal hyperplasia congenital)	Dermatitis, herpetiformis, bullous
Anemia, hemolytic, acquired (autoimmune)	Dermatitis, seborrheic, severe
Anemia, hypoplastic, congenital (erythroid)	Dermatomyositis, systemic
Anemia, red blood cell (erythroblastopenia)	Dermatoses, inflammatory, severe
Arthritis, psoriatic	Enteritis, regional (Crohn's disease)
Arthritis, rheumatoid	Erythema multiform, severe
Bowel disease, inflammatory, including colitis, ulcerative	Fever, due to malignancy
Bronchitis, asthmatic, acute or chronic	Gouty arthritis, acute
Calcium pyrophosphate deposition disease, acute (pseudogout, chondrocalcinosis articularis, synovitis, crystal-induced)	Hemolysis
Carcinoma, breast	Hepatitis, chronic active
Carcinoma, prostatic	Hepatitis, nonalcoholic, in women
Connective tissue disease, mixed	Hypercalcemia associated with neoplasms (or sarcoidosis)
Dermatitis, exfoliative	Increased cranial pressure, due to malignancy
Dermatitis, herpetiformis, bullous	Leukemia, acute or chronic
Dermatitis, seborrheic, severe	Lupus erythematosus, systemic
Dermatomyositis, systemic	Lymphomas, Hodgkin's or non-Hodgkin's
Dermatoses, inflammatory, severe	Multiple myeloma
Enteritis, regional (Crohn's disease)	Mycosis fungoides
Erythema multiform, severe	Necrosis, hepatic, subacute
Fever, due to malignancy	Pemphigoid
Gouty arthritis, acute	Penphigus
Hemolysis	Polychondritis, relapsing
Hypercalcemia associated with neoplasms (or sarcoidosis)	Polymyalgia, rheumatic
Increased cranial pressure, due to malignancy	Polyps, nasal
Leukemia, acute or chronic	Pulmonary disease, chronic obstructive
Lupus erythematosus, systemic	Reiter's disease
Lymphomas, Hodgkin's or non-Hodgkin's	Rheumatic fever
Multiple myeloma	Rhinitis, allergic, perennial or seasonal, severe
Mycosis fungoides	Thrombocytopenia secondary, in adults
Nausea and vomiting, cancer chemotherapy induced	Thrombocytopenia purpura, idiopathic, in adults
Pemphigoid	Trichinosis
Penphigus	Metoclopramide
Polychondritis, relapsing	Gastroparesis
Polymyalgia, rheumatic	Nausea and vomiting, cancer chemotherapy induced
Polyps, nasal	Phenytoin Sodium
Pulmonary disease, chronic obstructive	Epilepsy
Reiter's disease	Prochlorperazine Edisylate
Rheumatic fever	Nausea and vomiting
Rhinitis, allergic, perennial or seasonal, severe	Ranitidine hydrochloride
Thrombocytopenia, secondary, in adults	Adenoma, multiple endocrine
Thrombocytopenia purpura, idiopathic, in adults	Bleeding, upper gastrointestinal
Trichinosis	Hypersecretory conditions, gastric
Iron dextran	Mastocytosis, systemic
Iron deficiency anemia	Pancreatic insufficiency
Leucovorin calcium	Reflux, gastroesophageal
Methotresate toxicity (antidote to folic acid antagonist)	Stress-related mucosal damage
Mannitol	Ulcer, duodenal
Premeditation, cancer chemotherapy	Ulcer, gastric
Methylprednisolone sodium succinate	Zollinger-Ellison syndrome
Adrenocortical insufficiency, chronic primary (Addison's)	Biologics and Indications
Adrenocortical insufficiency, secondary	Immune globulin
Adrenogenital syndrome (adrenal hyperplasia, congenital)	Immunodeficiency syndrome
Anemia, hemolytic, acquired (autoimmune)	Thrombocytopenic purpur~ idiopathic
Anemia, hypoplastic, congenital (erythroid)	Alpha-proteinase inhibitor, human
Anemia, red blood cell (erythroblastopenia)	Emphysema panacinar, due to alpha-antitrypsin deficiency

Table C-2—Proposed List of Non-Covered Home IV Antibiotic Drugs and Indications

Antibiotic Drugs Not Proposed for Coverage	Conditions
Chloramphenicol sodium succinate	Biliary tract infections Central nervous system infections
Colistimethate sodium	Intra-abdominal infections
Doxycycline hyclate	Respiratory tract infections
Erythromycin gluceptate	Septicemia
Erythromycin lactobionate	
Kanamycin sulfate	
Lincomycin hydrochloride	
Minocycline hydrochloride	
Moxalactum disodium	
Oxytetracycline hydrochloride	
Polymyxin B sulfate	
Tetracycline hydrochloride	

6. Kanamycin sulfate
7. Lincomycin hydrochloride
8. Minocycline hydrochloride
9. Moxalactum disodium
10. Oxytetracycline hydrochloride
11. Polymyxin B sulfate
12. Tetracycline hydrochloride.

In addition, we want to note that, in our administrative process of assembling the list of antibiotic drugs (covered and noncovered), we believe that we have addressed all antibiotic drugs currently on the market. However, the introduction of new drugs into the marketplace is an ongoing occurrence. In addition, it is not inconceivable that in our process, we may have inadvertently missed an antibiotic drug. Therefore, we also invite public comment concerning antibiotics that do not appear in either appendix.

For non-antibiotic drugs, the Secretary has to make a determination that a drug can generally be safely and effectively administered in the home. Therefore, before and IV drug could be placed on Appendix I, we had to develop evidence from which that determination could be made. We derived this list based on consultations with the USP DI and the AHFS DI, providers of home IV therapy, and a review of available medical and scientific information.

With respect to the antineoplastic drug subcategory, we initially considered the following drugs for inclusion on the list:

1. Bleomycin sulfate
2. Cyclophosphamide
3. Cytarabine
4. Daunorubicin hydrochloride
5. Diethylstilbestrol diphosphate
6. Doxorubicin hydrochloride
7. Etoposide
8. Fluorouracil

9. Methotrexate sodium
10. Mitomycin
11. Mitoxantrone hydrochloride
12. Streptozocin
13. Vinblastine sulfate
14. Vincristine sulfate.

Concerns were raised throughout the process of developing and clearing the list about the general safety of this group of drugs when administered intravenously in the home setting. A review of the drug labels revealed that of the 14 drugs in this category, 12 of them had warnings that specified that the drug should be administered by or under the supervision of a qualified physician who is experienced in cancer therapy. In addition, several drugs had additional warnings that patients should have access to or be treated in a facility with laboratory and supportive resources sufficient to monitor drug tolerance. We also reviewed the National Institutes of Health (NIH) recommended guidelines for the "Handling of Parenteral Antineoplastic Drugs" prepared in collaboration with oncologists, the clinical center pharmacy (within NIH), oncology nurses, and National Cancer Institute staff. With these factors to consider, and mindful also of the extensive safety requirements these factors could necessitate in the conditions of participation for home IV drug providers, we concluded that we are not able to propose, at this time, that these drugs could be safely and effectively administered intravenously in the home. In order to be consistent with the approved FDA labeling, we made the decision to remove these drugs from [table C-1]. Because of the concern about whether antineoplastics are safe for use in the home, we have decided to seek further advice from the Public Health Service on this matter. Coverage of antineoplastic drugs under the home IV therapy benefit will accordingly be deferred pending receipt of such advice.

Use of Compendia—We selected the three compendia listed above as reliable sources for some of the advice and information we needed based on the recommendations contained in the Conference Report accompanying Pub. L. 100-360 (H.R. Report No. 661, 100th Congress, 2d Session 192 (1988)). In the report, the three compendia are suggested for consideration as references for a related purpose under the new drug benefit, that is, for purposes of the establishment of standards for covered outpatient prescription drugs, as required under the new section 1834(c)(5)(B) of the Act (as added by section 202(b)(4) of Pub. L. 100-360). Since Congress recognized these compendia as authoritative for one purpose under the new drug benefit, we believe it is appropriate to rely on them for a related similar purpose under that benefit.

In addition, the USP DI is sponsored by the USP, and organization that includes members of schools of medicine and pharmacy, State medical and pharmacy associations, national medicine and pharmacy associations. Its

listing of drugs includes virtually all drugs approved in the United States. The USP DI staff prepare monographs after a literature search and review of FDA approved labeling. (A monograph is an essay or treatise on the available data for a specified drug.) These monographs are reviewed by over 300 additional experts, plus many schools, associations, pharmaceutical companies, and government agencies. They are again reviewed by advisory panels until a consensus is developed. Proposed monographs are then published in the USP DI Review for general public comment before being published in the USP DI. The USP DI is republished annually with six supplements per year and contains individual monographs, most information from the FDA-approved label, and unlabeled uses of approved drugs.

The AHFS DI is sponsored by the American Society of Hospital Pharmacists, which represents 22,000 pharmacists. AHFS DI staff prepare monographs after a literature search and review of FDA labeling. These monographs are reviewed by over 300 specialists at the doctoral level, including physicians, pharmacologists, and biochemists selected from among experts in drug therapy. This review process continues until a consensus is developed. The AHFS DI includes individual drug monographs with some general category statements, full FDA label disclosure, and unlabeled uses of approved drugs. The AHFS DI is republished annually with three to four supplements per year.

The ANA DE is sponsored by the AMA, which represents over 293,000 physicians. The listed drugs include all drugs approved by the FDA for use in the United States. AMA staff prepare monographs after a literature search and review of FDA approved labeling. These monographs are reviewed by about 400 consultants followed by approximately 100 designees or members of the American Society for Clinical Pharmacology and Therapeutics. The review process continues until a consensus is developed. The AMA DE includes mostly general statements with truncated drug monographs including unlabeled uses of approved drugs. The AMA DE has been published every 3 years with updates. However, beginning in late 1989, the AMA plans to publish this compendium annually with quarterly updates.

Description of the List

[Table C-1] consists of IV drugs and their indications divided into three main categories. The categories are: biological, antibiotics and non antibiotics (which is further broken down as indicated above into the four subcategories of drugs, excluding for reasons discussed above antineoplastic drugs). The list is based on our analysis and evaluation of the recommendations and information received from the various professional organizations that we contacted. [Table C-2 contains a list] of

the antibiotic drugs and indications not proposed for coverage.

We recognize that there is wide variation in both the type of drugs included in [table C-1] as well as the indications for these drugs. This is due in part to the fact that the concept of home IV therapy has evolved to treat diverse types of patients:

- Patients who began a course of IV therapy in the hospital that has not been completed, but who are stable enough to no longer require hospitalization.
- Patients who are terminally ill and require IV therapy, but whose condition does not warrant hospitalization.
- Other types of patients who require IV therapy but do not require hospitalization.

We are proposing that all candidates for home IV therapy meet specific selection criteria as outlined in the regulations referred to earlier that deal with coverage of home IV drug therapy services and conditions of participation for home IV drug therapy providers.

While many of the drugs on the proposed list can be safely and effectively administered in the home setting and would be covered, such medications are sometimes taken orally. Payment may be denied if a more appropriate route of administration is available. When deciding that the route of administration is appropriate, the Peer Review Organization (PRO) will carefully review to determine if another route of administration would be effective (for example, oral, subcutaneous, etc.). If the PRO makes a determination that another route would be effective, the PRO would deny payment. (An example might be: a physician seeking prior approval for the administration of intravenous Aminophylline.) Payment is made for home IV therapy only when it is reasonable and necessary and there is medical justification for its use.

The proposed list includes some very toxic drugs while other less toxic drugs are excluded. We note, however, that in urging us to include virtually all IV drugs on the list, some organizations we contacted took the position that “a drug is a drug, and a cell is a cell.” These organizations believe a drug that can be administered in a hospital setting can also be administered in the home setting. We take a different view. There are a variety of factors that we have considered that play a role in the determination of whether a drug is safe and effective for use in the home. These factors include, in addition to the obvious factor of potential serious or life-threatening side effects, drug product stability and compatibility characteristics, and the need for close patient monitoring.

The variation of indications for each specific drug is a reflection of the varying degrees and stages of illnesses that will be treated in the home setting. We believe that we must allow flexibility to enable the physician to develop

a plan of treatment appropriate for the specific medical condition of the patient. Nevertheless, we wish to make clear that the appearance of an indication for a covered drug on the listing is not intended to imply that the indication is approved under the provisions of the FDCA.

With respect to the specific working of the indications, because there are different phrases to describe the same disease states and conditions, there may appear to be inconsistencies in our use of medical terminology when listing indications. According to medical professionals and medical texts, the following terms are examples of terms that may be used interchangeably:

- . Genitourinary infections with gynecological infections; and
- . Skin and soft-tissue infections with skin and skin structure infections.

Also, there may be times when a specific indication could be considered as a subset of a larger classification. Examples of these would include:

- Cystitis as part of urinary tract **infections; and**
- . Gonorrhea as part of genitourinary infections.

Such indications may have been listed separately in Appendix I because that is the way they appeared in the recommendations that we received. In addition, because the practice of medicine is dynamic, it would not be feasible to list all indications, either labeled or unlabeled, that are not suitable for treatment in the home. For this reason, we have listed the indications for each drug that can generally be treated safely and effectively in the home. The following indications are proposed for exclusion for all intravenous antibiotics because it is our understanding that the seriousness of the condition requires hospitalization.

1. Biliary tract infections.
2. Central nervous system infections.
3. Intra-abdominal infections.
4. Respiratory tract infections.
5. Septicemia.

Furthermore, specific labeled indications for certain drugs have been excluded because it is our understanding that they could not be safely and effectively treated intravenously in the home.

One of our proposed subcategories is “hydration therapy.” For our purposes and purposes of home IV therapy, the term is defined as the replacement of fluids or electrolytes, or both, in the human body when the physiologic and homeostatic mechanisms, which normally preserve their balance, fail as a result of illness or disease.

Most of the drugs that appear on the proposed list have specific dosages or dose ranges and are given at specific time intervals. For example, Cimetidine, used for hypersecretory conditions has a recommended dosing schedule of 300 mg administered intravenously every 6-8 hours. In comparison, for hydration therapy purposes, a physician can prescribe any of numerous available solutions used for this purpose, with the addition of one or more of the listed electrolytes, in a dose he or she has determined to be appropriate (for example, dextrose 5 percent in sodium chloride 0.45 percent, 1000 ml with 7 mEq of calcium as the chloride, gluconate or gluceptate salt).

The magnitude of different combinations of ingredients in this subcategory requires our format for listing drugs in hydration therapy to differ from the other categories. This means that the options available to a physician prescribing a course of hydration therapy for a Medicare beneficiary would not be limited. The only restrictions on amounts of ingredients are those placed on solutions. These limitations have been determined to be the upper limits of commercially available products that would normally be used for hydration therapy (versus parenteral nutrition).

We are aware that our list will need periodic revision as new drugs are approved by FDA for entry in the marketplace. The FDA has informed us that 10-20 new IV drugs are approved over the course of each year that we would have to consider for entry on the list. In addition, if a drug already on the list is removed from the market or if a drug is no longer considered to be appropriate for home use, we would delete the drug from the list. We will update the list at least annually through a notice in the *Federal Register*. Updates may occur more frequently, possible as often as semi-annually.

Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed notice that meets one of the E.O. criteria for a “major rule”; that is, that would be likely to result in:

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Also, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (REA) (5U.S.C. 601 through 612) unless the Secretary certifies that a proposed notice would not have a

significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmaceutical manufacturers and physicians are considered small entities.

As noted earlier in this preamble, this notice addresses the issues of:

1. Identifying IV drugs (both antibiotics and non-antibiotics) and their indications that are approved for marketing by FDA; and
2. Identifying those IV drugs that are safe and effective for use in the home. There maybe some economic or other effects of the proposed list of drugs that may touch upon other proposed rules implementing other home IV provisions of the catastrophic legislation, and some of these effects are addressed here as well as in the other rules. The purpose of this duplication is to ensure that the reader may determine the effects of each document without referring to the other proposed documents.

In addressing the first issue discussed above, all of the IV drugs listed in this notice may be covered under Medicare as covered outpatient drugs because they meet the criteria defined in section 1861(t)(2) of the Act. Thus, HCFA has exercised no administrative discretion in this area.

Administrative discretion, however, was required to identify those IV drugs that are safe and effective for use in the home. As discussed earlier in this preamble, we contacted the USP, ASHP, AMA, various home IV providers, the Pharmaceutical Manufacturers Association, various drug manufacturers and the Intravenous Nurses Society in making our initial determination as to whether a certain IV drug could be proposed as safe and effective for use in the home. We believe that the information solicited from the compendia along with the advice of the other organizations constitutes a valid basis on which to conclude with reasonable assurance that a particular drug can generally be administered safely and effectively in a home setting. Furthermore, we believe that the identification of IV drugs that are safe and effective for use in the home would not result in any significant effects on the economy or on small businesses. Our reasons follow:

Effects on Drug Manufacturers-Drug manufacturers producing IV drugs that are included in this proposed list would be advantaged in competing for the Medicare market because their drugs would be covered under Medicare as home IV drugs. We recognize that manufacturers producing IV drugs that are not included in our proposed list would be adversely affected in competing for the Medicare share of the IV drug market. Although we do not have data available that allow us to determine the degree to which drug manufacturers would be

affected, we do not believe **that will be significantly affected. This is because IV drugs (except antineoplastics) currently being prescribed for home use would likely be included on the proposed list based on the methodology used in developing this list.**

Effects on Beneficiaries-Medicare beneficiaries who are prescribed an IV drug for home use that is on the proposed list would benefit by being eligible for Medicare coverage of that drug. Conversely, beneficiaries for whom a drug has been prescribed that is not covered by Medicare for home IV use may have to remain in the hospital to receive covered IV therapy or may have to incur expenses for home IV therapy themselves. Since we believe that most drugs currently prescribed for home IV use are included on the list, we do not believe beneficiaries would be significantly affected adversely.

Effects on Physician-If drugs commonly prescribed by a physician for use in the home are not on the list, the physician could be influenced to change his or her prescribing patterns for Medicare patients to ensure that the patient is prescribed a Medicare covered home IV drug. However, given that we have consulted with various professional organizations and compendia in developing this list, we believe that the list, with the exception of antineoplastics, contains the most frequently prescribed home IV therapy drugs. Thus, we believe it unlikely that physicians' prescribing patterns would change significantly as a result of this list.

For the reasons discussed above, we believe that this notice would not meet the \$100 million criterion nor do we believe that it meets the other E.O. 12291 criteria. Therefore, we have determined that this notice is not a major rulemaking document under E.O. 12291, and a regulatory impact analysis is not required. Also, for the reasons discussed, we have determined, and the Secretary certifies, that this notice would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis would not be required under RFA.

Payment for Covered Outpatient Drugs (54 F.R. 37208)

This proposed rule sets forth the methodology for determining payment for covered outpatient drugs under the new catastrophic drug benefit. This proposal would implement sections 1834 (c)(2), (3), and (4) of the Social Security Act as added by section 202(b) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for these covered outpatient drugs under Part B of Medicare would be implemented on January 1, 1990 for drugs used in immunosuppressive therapy and covered home intravenous (IV) drugs and on January 1, 1991 for all other drugs.

Purpose

This subpart implements section 1834(c) of the Act in part by specifying how payments are made for covered outpatient drugs under the catastrophic drug benefit.

Definitions

For purposes of this subpart, the following definitions apply: **Average price** means the price that is determined through the use of either published or survey data concerning amounts pharmacies pay for drug products. **Multiple source drug** means a covered outpatient drug for which there are two or more drug products that meet all of the following conditions during payment calculation period:

- (a) Therapeutically equivalent. The drug products are rated as therapeutically equivalent by the Food and Drug Administration (FDA) in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."
- (b) Pharmaceutically equivalent and bioequivalent
 - (1) Except as provided in paragraph (b)(2) of this section, the drug products have been determined by FDA to be pharmaceutically equivalent and bioequivalent.
 - (2) The drug products are not required to meet the condition concerning pharmaceutically equivalency and bioequivalency as set forth in paragraph (b)(1) of this section if FDA changes by regulation (after an opportunity for public comment of 90 days) the requirement that, for Purposes of the Approved Drug Products with Therapeutic Equivalence Evaluations," in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.
- (c) Available for sale or marketing. The drug products are considered to be available for sale or marketing. Drug products meet this condition if they are listed by FDA in its most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (other than in the Discontinued Drug Product List in the publication) unless HCFA determines that sale or marketing is not actually occurring.

Nonmultiple-source drug means a covered outpatient drug that does not meet the definition of a "multiple-source drug." Payment calculation period means the 6-month period beginning January 1st of each year or the 6-month period beginning July 1st of each year.

Determination of Amount Payable

- (a) General. The amount payable for a covered outpatient drug under the catastrophic drug benefit

as described in 410.29 of this chapter is the applicable payment percent for the drug as determined under 414.514 multiplied by the lesser of:

- (1) The actual charge; or
- (2) The payment limit determined under 414.506.

- (b) Effective date. Payment is determined under the **criteria** described in paragraph (a) of this section for:

- (1) Drugs dispensed for immunosuppressive therapy after a transplant or covered home IV drugs on or after January 1, 1990; and
- (2) All other covered outpatient drugs dispensed on or after January 1, 1991.

Determination of the Payment Limit

- (a) General. To determine the payment limit for a drug, HCFA uses the procedures set forth in paragraph (b) or (c) or this section.
- (b) Nonmultiple-source drug and multiple-source drug with a restrictive prescription. For a nonmultiple-source drug and multiple-source drug with a restrictive prescription as described in 414.508, the payment limit is determined as follows:
 - (1) For drugs dispensed on or after January 1, 1990 and before January 1, 1992, the payment limit is equal to the sum of:
 - (i) The amount of the administrative allowance as set forth in 414.512; and
 - (ii) The product of the number of tablets or other dosage units dispensed and the dosage unit average price as determined in 414.510 for the payment calculation period in which the drug is dispensed.
 - (2) For drugs dispensed on or after January 1, 1992, the payment limit is equal to the lesser of:
 - (i) The **amount** of the administrative allowance plus the product of number of tablets or other dosage units dispensed and the average price per dosage unit determined under 414.510 for the payment calculation period in which the drug is dispensed; or
 - (ii) The 90th percentile of actual charges for a drug for the second previous payment calculation period or other dosage units dispensed.
- (c) Multiple-source drug without a restrictive prescription. For a multiple-source drug without a restrictive prescription, the payment limit is equal to the sum of:

- (1) The administrative allowance; and
- (2) The product of the number of tablets or other dosage units dispensed and the dosage unit average price based on the unweighed median determined under 414.510 for the payment calculation period in which the drug is dispensed.

Determining Whether a Prescription Is Restrictive:

- (a) General. A drug has a restrictive prescription if it meets the conditions set forth in either paragraph (b) or paragraph (c) of this section.
- (b) Handwritten prescription. In the case of a written prescription for a drug, only if the prescribing physician (or other person prescribing the drug) includes in his or her handwriting the phrase “brand medically necessary.”
- (c) Telephoned prescription. In the case of a prescription for a drug that is telephoned to the pharmacy, the prescribing physician (or other legally authorized person who is prescribing the drug) indicates that the particular drug must be dispensed by stating the phrase “brand medically necessary” both:
 - (1) During the telephone call; and
 - (2) Within 30 days after the telephone call, in a written and signed confirmation, in his or her handwriting to the pharmacy.

Determination of Dosage Unit Average Price

- (a) General. HCFA determines the average price on a per dosage unit basis for purchases in reasonable quantities, as appropriate, based on prices in effect on the first day of the previous payment calculation period. The average price is based on dosage form and strength for each drug product.
- (b) Sources for dosage unit average price. HCFA obtains the information described in paragraph (a) of this section from the lower of:
 - (1) When available, a biannual survey of a representative sample of direct sellers, wholesalers, or pharmacies as appropriate; or
 - (2) Prices published in commonly recognized, comprehensive listings of drug prices.
- (c) Performance of surveys.
 - (1) Nonmultiple-source drugs.
 - (i) HCFA performs the biannual survey described in paragraph (b)(1) of this section for those nonmultiple-source drugs that are commonly prescribed to Medicare beneficiaries except that this survey does not have to be performed in:
 - (A) Any year in which HCFA determines that a survey is not appropriate for a

- specific covered outpatient drug; or
 - (B) In years subsequent to 1990, any year in which HCFA determines that there is a low volume of sales for a drug.
 - (ii) The dosage unit average price is based on the median of the surveyed prices.
- (2) Multiple-source drugs. HCFA performs the biannual survey described in paragraph (b)(1) of this section for multiple-source drugs, but only if HCFA determines a survey to be appropriate. The dosage unit average price is based on the unweighed median of the surveyed prices.

- (d) Use of published prices.
 - (1) Nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions. The dosage unit average price for nonmultiple-source drugs and multiple-source drugs with restrictive prescriptions is based on the lowest published price.
 - (2) Multiple-source drugs without restrictive prescriptions. The dosage unit average price for multiple-source drugs without restrictive prescriptions is based on the unweighed median of published prices.
- (e) National determination. The determination of the dosage unit average price is made on a national basis unless HCFA makes the determination on a regional basis to take into account limitations on the availability of drugs and variations on the prices among different areas.
- (f) Discounts. In determining the dosage unit average price, HCFA does not consider discounts.

Administrative Allowance

- (a) For 1990 and 1991. For a drug dispensed on or after January 1, 1990 and before January 1, 1992, the administrative allowance for dispensing the drug is:
 - (1) \$4.50 per prescription for a pharmacy that meets the requirements under subpart B of part 490 of this chapter for a participating pharmacy; or
 - (2) \$2.50 per prescription for a pharmacy that is not a participating pharmacy.
- (b) For years subsequent to 1991. For each year subsequent to 1991, the administrative allowance is the allowance applicable to the previous year increased by the percentage increase in the implicit price deflator for gross national product over the 12 month period ending with August of the preceding year as published by the Department of Commerce rounded to the nearest penny.

- (c) Limitation on administrative allowance for dispensing insulin.
 - (1) **Purchase of a 30 day supply.** For insulin that is available without a prescription, the administrative allowance is made for each purchase of a reasonable quantity, that is, a 30 day supply.
 - (2) Exceptions. An administrative allowance is made for a purchase of a supply of insulin for fewer than 30 days in the following circumstances (or if other extenuating conditions exist):
 - (i) There is a change in the type of insulin the beneficiary uses or the insulin regimen is otherwise modifies; or
 - (ii) If, because of travel plans, the beneficiary needs to make smaller purchases or forgets to bring along enough insulin for duration of the trip.
- (d) Exception for drugs dispensed for home IV drug therapy. No administrative allowance is paid for dispensing a drug that is to be used in home IV drug therapy. An allowance for dispensing IV drugs is made under the fee schedule for payment for services related to home IV drug therapy under subpart J of part 414.

Amount of the Payment Percent

- (a) Immunosuppressive and home IV drugs. **For drugs related to immunosuppressive drug therapy dispensed during the first year after a covered organ transplant and for home IV drugs, the payment percent equals 80 percent.**
- (b) Other drugs. The payment percent for covered outpatient drugs other than the drugs described in paragraph (a) of this section equals the following:
 - (1) In 1990 and 1991, 50 percent.
 - (2) In 1992, 60 percent.
 - (3) In 1993 and subsequent years, 80 percent.

Coverage of Home Intravenous Drug Therapy Services (54 F.R. 37422)

These proposed regulations would expand coverage under Medicare Part B to include coverage of home IV drug therapy services as authorized by section 203 of the Medicare Catastrophic Coverage Act of 1988. They include requirements for certification and for review and approval of the need for the covered services by a peer review organization, and they place limits on acceptance of and payments for certain patient referrals for covered home IV drug therapy services as specified in the statute. Home IV drug therapy services are covered by Medicare beginning January 1, 1990.

Basic Rule

Under sections 1834(d) and 1861(jj), Medicare Part B pays for home intravenous drug therapy services furnished by a qualified home intravenous drug therapy provider (see part 485, subpart C of this chapter) or by others under arrangements made by the qualified home IV drug therapy provider with them, to a patient who is under the care of a physician, in a place of residence used as the beneficiary's home and under a plan of care established and periodically reviewed by the beneficiary's referring physician.

Definitions

For purposes of this subpart:

Home intravenous drug therapy provider or "home IV provider" means an entity that provides home IV drug therapy services, has been certified as meeting the conditions of participation of part 485, subpart C of this chapter, and has a provider agreement with HCFA.

Home intravenous drug therapy services or "home IV services" means nursing, pharmacy and related services (including medical supplies, equipment, intravenous fluids only when used as diluents for covered home IV drugs, and delivery services) necessary to conduct an intravenously administered regimen safely and effectively in conjunction with the use of a covered home intravenous drug. These services are furnished to an individual who is under the care of a physician, in a place of residence used as the individual's home, by a qualified home IV provider (or by others under arrangements), and under a plan established and periodically reviewed by the referring physician.

IV stands for intravenous.

Place of residence used as the individual's home is a place in which the beneficiary normally resides and is not an institution or facility that is defined in section 1861(e)(1), 1819(a) or 1919(a) of the Act.

Referring physician means the physician who prescribed the covered home intravenous drug for which the services are to be provided or who established the plan of care for the services or both.

Home IV Drug Therapy Services

- (a) Individual services. Particular services included in the term "home intravenous drug therapy services" that are covered under this subpart are limited to the nursing services and pharmacy services described in 485.135 and 485.140, respectively, of this chapter and related services described in paragraph (b) of this section that are necessary for the safe and effective administration of a covered home IV drug. Separate payment may not be made for any of these services furnished to

- a patient receiving covered home intravenous drug therapy services.
- (b) Related services and supplies. The home IV provider must furnish the following if they are necessary for the safe and effective administration of a covered home IV drug:
 - (1) Medical supplies;
 - (2) Intravenous fluids for use as diluents for covered home IV chug;
 - (3) Training of the patient or his or her caregiver in the techniques of IV drug therapy;
 - (4) Equipment such as IV poles and infusion pumps; and
 - (5) Delivery of medical items and supplies.
- (c) Prohibited payment. Payment may not be made to a home IV provider for covered home IV drug therapy services unless the home IV provider furnishes the covered home IV drug either directly or under arrangements.

Payment Limitations Concerning Certain Patient Referrals

- (a) Ownership and compensation rules. Payment may not be made to a home IV therapy provider for the home IV drug therapy services furnished to a beneficiary if that beneficiary's referring physician or an immediate member of the referring physician's family has an ownership interest in the provider or receives compensation from the provider unless an exception under paragraph (b) through (e) of this section applies. For purposes of this paragraph, an immediate member of the family includes the physician's spouse; natural and adoptive parents, natural and adopted children; natural, adopted, and adoptive siblings; stepparents, stepchildren, and step siblings; fathers-in-law, mothers-in-law, brothers-in-law, sisters-in-law, sons-in-law, and daughters-in-law; and grandparents and grandchildren.
- (b) Exception applying to limitation on ownership.
 - (1) Payments may be made if the ownership interest is the ownership of stock in the home IV provider that is traded over a publicly regulated exchange and purchased on terms generally available to the public.
 - (2) Payments may be made if the provider is the sole home IV drug therapy provider in a rural area.
 - (3) For purposes of paragraph (b)(2) of this section, a rural area is one that is not an urbanized area (as defined by the Bureau of the Census) and that is designated by the Secretary either:
 - (i) As an area with a shortage of personal health services under section 1302(7) of the Public Health Service Act, or
 - (ii) As a health manpower shortage area described in section 332(a)(1)(A) of the Act because of its shortage of primary medical care manpower.
- (4) For purposes of paragraph (b)(2) of this section, a sole home IV drug therapy provider in a rural area is one that is approved as such by HCFA after the provider:
 - (i) Designates a particular area;
 - (ii) Shows that no other home IV provider furnishes services within that area [and]
 - (iii) Shows that there are no physicians without an ownership interest in the provider available to perform certification and recertification and to write plans of care.
- (c) Exception applying to limitation on compensation. Payment may be made under this section if the compensation is reasonably related to items or services actually provided by the physician and does not vary in proportion to the number of referrals made by the referring physician. This exception does not apply if the compensation is for direct patient care services.
- (d) Exception applying to uncompensated officer or director. Payment may be made if the referring physician's or immediate family member's ownership or financial relationship with the provider is as an uncompensated officer or director of the provider.
- (e) Exceptions applying to instances in which there is not substantial risk of program abuse. Payment may be made under this part in those cases in which the Secretary has specifically determined that the nature of the ownership or compensation does not pose a substantial risk of program abuse involving the following:
 - (1) Space rental. For purposes of this paragraph, the term "fair market value" means the value of the rental property for general commercial Purpose (not taking account of its intended use), but it is not adjusted to reflect the additional value the prospective lessee or lessor value would attribute to the property as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. As used in section 1834(d) of the Act, neither "ownership" nor "compensation" includes payments made by a lessee to a lessor for the use of premises, as long as:
 - (i) The lease agreement is set out in writing and signed by the parties;
 - (ii) The lease specifies the premises covered

- by the lease;
 - (iii) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, their periodicity, and the exact rent for such intervals;
 - (iv) The term of the lease is for not less than 1 year; and
 - (v) The rental charge is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals of business between the parties for whom the services would be paid by Medicare or Medicaid.
- (2) Equipment rental. For purposes of this paragraph, the term “fair market value” means the value of the equipment when obtained from a manufacturer or professional distributor, but it is not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the equipment as a result of its proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee. As used in section 1834(d) of the Act, neither “ownership” nor “compensation” includes payments made by a lessee of equipment to the owner (‘lessor’ of the equipment for the use of the equipment, as long as:
- (i) The lease agreement is set out in writing and signed by the parties;
 - (ii) The lease specifies the equipment covered by the lease;
 - (iii) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, their periodicity, and the exact rent for such intervals;
 - (iv) The term of the lease is for not less than 1 year; and
 - (v) The rental charge is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals of business between the parties reimbursed under Medicare.
- (3) Personal services and management contracts. For purposes of this paragraph, an agent of a principal is any person, other than a bona fide employee, who has an agreement to perform services for, or on behalf of, the principal. As used in section 1834(d) of the Act, neither “ownership” nor “compensation” includes payments made by a principal to an agent as compensation for the services of the agent, as long as:
- (i) The agency agreement is set out in writing and signed by the parties;
 - (ii) The agency agreement specifies the services to be provided by the agent;
 - (iii) If the agency agreement is intended to provide for the services of the agent on periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, the periodicity, and the exact charge for such intervals;
 - (iv) The term of the agreement is for not less than 1 year; and
 - (v) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in manner that takes into account the volume or value of any referrals of business between the parties that is reimbursed under Medicare or any State health care program.
- (4) Employees. As used in section 1834(d) of the Act, neither “ownership” nor “compensation” includes any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the provision of covered items or services. For purposes of this paragraph (f)(4), the term “employee” has the same meaning as it does for purposes of 42 U.S.C. 410(j)(2), part of the statutory definition of “employee” in the Federal Insurance Contributions Act; that is, the common law employment test.

Physician Certification and Plan of Treatment Requirements

Medicare Part B pays for home intravenous drug therapy services only if the referring physician certifies, and recertifies as required under paragraph (b) of this section, that the requirements described in paragraphs (a)(1) through (a)(5) of this section are being met.

- (a) Certification: Content. The referring physician must certify, or recertify if applicable, that:
 - (1) The home intravenous drug therapy services

- are or were required because the individual needs or needed the services for the administration of a covered home intravenous drug;
- (2) A plan for furnishing the services has been established by the referring physician and is reviewed periodically by that physician;
 - (3) The services are or were furnished while the individual is or was under the care of a physician;
 - (4) The services are furnished in a place of residence used as the patient's home; and
 - (5) For services initiated before January 1, 1993, a PRO has approved the services in accordance with part 466, subpart E, of this chapter.
- (b) Recertification. The referring physician must recertify that the requirements in paragraph (a) of this section are still met at least every 30 days.
- (c) Plan of care requirements.
- (1) Establishment. The referring physician must establish and sign the plan of care and consult as necessary with the home IV provider nurse or pharmacist before the home IV Therapy begins in accordance with sections 485.135 and 485.140 of this chapter.
 - (2) Content. The plan of care must contain at least the information required in section 485.120 of this chapter.
 - (3) Review. The physician must review and sign the plan of care at least every 30 days.

PRO Review of Home IV Drug Therapy Services

- (a) Statutory basis. Sections 1154(a)(16) and 1835(a)(2)(G) of the Act require PROS to review all home intravenous (IV) drug therapy services before these services begin; or, in the case of services first initiated on an outpatient basis, within one working day (other than in exceptional circumstances) of the date of initiation of the services.
- (b) Applicability. The regulations in this subpart apply to reviews, conducted by a PRO and its subcontractors, of home IV drug therapy services furnished, or proposed to be furnished to all Medicare beneficiaries other than those beneficiaries enrolled in HMOs [health maintenance organizations] or CMPs [competitive medical plans] that contract with HCFA on a risk-basis as described in subpart C of 42 CFR part 417.

Effective Dates-All home IV drug therapy services intended to be furnished to Medicare beneficiaries on or after January 1, 1990 are subject to the PRO review requirements of this subpart.

Definitions-As used in this subpart:

Outpatient basis means the patient receives services other than as an inpatient of a hospital.

Scope of PRO Review—

- (a) General rule. After a PRO receives a request for review of home IV drug therapy services from either the referring physician or the health care facility, the PRO must determine (in accordance with the terms of its contract) whether the home IV drug therapy is reasonable, appropriate, and necessary for the treatment of the illness or injury. This review includes a determination that the intravenous route of administration is the correct route of administration and that the home IV drug therapy services meet professionally recognized standards of care.
- (b) Coordination of sanction activities. In implementing review of home IV drug therapy services, PROS must carry out the responsibilities specified in subpart C, part 1004, chapter V of this title, regarding imposition of sanctions on health care facilities and practitioners who violate their statutory obligations under Section 1156 of the Act. For example, a PRO is to refer to the HHS [U.S. Department of Health and Human Services] Office of Inspector General a case involving a physician who exhibits a pattern of not correctly monitoring, by appropriate laboratory tests, the administration of a drug.

Notification of PRO Review Procedures-

- (a) Criteria. The PRO must distribute, at no charge, the criteria/quality screening guidelines to be used in screening cases, at a minimum, to all affected health care facilities and medical societies in the State.
- (b) Information required. Each PRO must give timely written notification to health care facilities and physicians in its State the following information:
 - (1) Date. The date upon which the PRO plans to begin review of home IV drug therapy services.
 - (2) Manner. The manner in which the referring physician or health care facility is to seek PRO review.
 - (3) Required information. The information to be furnished to the PRO by the physician and/or health care facility and the need for expediency in responding to PRO questions.
 - (4) Validation and quality review. The validation and quality review that the PRO may conduct on a sample of the cases after the services are furnished in the home.
 - (5) Financial liability. A general statement about

financial liability for charges related to home IV drug therapy services that are found to be not reasonable or medically necessary and a statement that no claims will be paid without PRO approval.

Responsibilities of Physicians and Health Care Facilities—

- (a) Physicians. The referring physician must cooperate (in addition to the requirements in 466.78) in the conduct of PRO review as follows:
 - (1) The physician must, in accordance with PRO-issued procedures, either seek PRO prior authorization for the drug he or she proposes to have administered intravenously at home or assist in providing necessary information in support of a health care facility that seeks PRO approval.
 - (2) The physician must furnish relevant medical records, upon request, to the PRO for any of the reviews described in this subpart.
- (b) Health care facilities.
 - (1) In addition to the general requirements for health care facilities set forth in 466.78, the health care facility must cooperate in the conduct of PRO review (in accordance with the regulations in this part and PRO-issued procedures) by obtaining the authorization number provided by the PRO:
 - (i) Before beginning the administration of an IV drug in the patient's home, except in cases where the drug is to be started on an outpatient basis on a weekend (i.e., a non-workday), the authorization must be obtained the first working day thereafter; and
 - (ii) In certain cases, before continuation of home IV drug therapy that the PRO has previously approved as described in 466.216 (c) and (d).
 - (2) Health care facilities must maintain a written agreement with the appropriate PRO.
 - (3) The health care facility must, in accordance with PRO-issued procedures, either seek PRO approval of the IV drug therapy services proposed to be administered at home or assist in providing necessary information in support of a referring physician that seeks PRO approval.
 - (4) The health care facility must transfer relevant medical records (including the plan of care described in 424.28(c)), upon request, to the PRO for any of the reviews described in this subpart.

Lack of Cooperation by a Health Care Facility or Physician—If a health care facility or physician fails to comply with the requirements for review set forth in this subpart, the PRO may determine that the health care facility or physician has failed to comply with the requirements of subpart C, part 1004, chapter V of this title concerning failure by providers or practitioners to meet statutory obligations under section 1156 of the Act and may report the matter to the Office of Inspector General.

PRO Designation—

- (a) When home IV drug therapy is proposed for a currently hospitalized inpatient, the referring physician or health care facility must contact, for prior authorization, the PRO with whom the hospital has an agreement.
- (b) When home IV drug therapy is proposed for a patient who has had the drug started on an outpatient basis, the physician or health care facility must contact, for authorization, the PRO for the State in which the home IV drug therapy provider is located.
- (c) For all other reviews, the PRO for the State in which the home IV drug therapy provider is located will conduct the review.

PRO Approval—

- (a) Before approving the home IV drug therapy services, the PRO must assured:
 - (1) **That the patient's condition is such that inpatient hospitalization is not justified either**
 - (i) As a continuation of an existing hospitalization; or
 - (ii) As a medically necessary and appropriate admission;
 - (2) Orally, in writing, or from documentation (or any combination of these three), that the patient meets the selection criteria outlined in 485.115 of this subpart;
 - (3) That the patient or caregiver has been or will be sufficiently trained as to how to administer the drugs safely and effectively in the home; and
 - (4) That the patient or caregiver has or will independently administer(e-d) intravenously at least one dose of the drug under supervision.
- (b) The PRO must determine that:
 - (1) **The plan** of care, executed by the referring physician, has enough information to support the coverage of home IV drug therapy services;
 - (2) The drug is being used for one of the stated indications listed in a **Federal Register** notice issued by the Secretary;

- (3) The drug is medically indicated for the treatment of the patient's condition;
 - (4) The dosage is correct (e.g., adjusted for height and body weight);
 - (5) Appropriate diagnostic studies (e.g., culture and sensitivities, kidney function tests) have been performed and will be performed as appropriate while the patient is receiving the therapy;
 - (6) Other appropriate periodic monitoring has been and will be performed;
 - (7) The drug is not contraindicated (e.g., based upon abnormal laboratory findings, or drug interactions); and
 - (8) The home IV drug therapy services meet professionally recognized standards of care.
- (c) The PRO must also determine that the intravenous route of administration is the only route of administration that will be effective.
- (d) In performing review, the PRO uses review coordinators to compare the facts about the individual case to the criteria/screening guidelines developed by HCFA, the PRO, or both.
- (1) If the case meets the criteria/guidelines, the review coordinator issues a PRO approval number.
 - (2) If the case does not meet the criteria/guidelines, the review coordinator refers the case to a PRO physician.
 - (3) The PRO physician review either approves the case (using a PRO approval number) or questions the case.
 - (4) If the case is questioned by the PRO physician, the physician who prescribed the home IV drug therapy and the health care facility are immediately given an opportunity to discuss the case.
 - (i) The PRO attempts to contact either the referring physician or health care facility.
 - (ii) The referring physician may discuss the case with a PRO physician.
 - (iii) The health care facility may discuss the case with a PRO representative. If, however, the health care facility designates a physician representative, the physician may also discuss the case with a PRO physician.
 - (iv) For potential quality problems, the PRO follows the timeframes outlined in its contract with HCFA.
- continued at home after a hospital stay, to authorize such use before hospital discharge.
- (2) The review must be requested by the referring physician or the health care facility in accordance with PRO-issued instructions.
 - (3) The PRO will follow the review process outlined in 466.214(c).
 - (4) The PRO must complete the review within one working day of receipt of a request for review.
 - (i) The date of the request for review is considered to be the date upon which the PRO receives all of the information it needs to complete the review.
 - (ii) In this timeframe, the PRO must give the health care facility and referring physician an opportunity to discuss the case as described in 466.214.
 - (iii) Failure of the health care facility and referring physician to discuss the case within the time allowed is not a basis that will prevent the PRO from making its determination base upon the information in its possession.
- (b) Initial review of IV drugs started on an outpatient basis. In the case of a patient whose IV drug therapy services are initiated on an outpatient basis, the referring physician or health care facility will request PRO approval no later than the first working day on which the home IV drug therapy services are prescribed.
- (1) The PRO has 8 working hours in which to complete its review after receipt of a request for review from the referring physician or health care facility.
 - (2) The date the PRO receives the request for review is the date on which the PRO receives all the information it needs to complete the review.
 - (3) PRO review follows a request from the referring physician or health care facility that is made in accordance with PRO-issued instructions.
 - (4) The PRO will follow the review process outlined in 466.214(c).
 - (5) The PRO must complete its review within 1 working day of initiation for the home IV drug services.
 - (i) This timeframe includes the time the PRO must give the health care facility and physician to discuss the case as described in 466.214.
 - (ii) If the health care facility and physician do not take advantage of the opportunity to discuss the review within the time allowed the PRO may make its determination

Timing of Review—

- (a) Prior review of continuation of inpatient hospital therapy.
 - (1) The PRO is required, for all IV drug therapy

based upon the information in its possession.

- (c) Subsequent reviews for continuation of drugs. In accordance with the PRO's prior approval, when drugs are to be continued for a period of time beyond the date or number of days approved by the PRO, the PRO will periodically review to determine that coverage of the home IV drug therapy services continues to be appropriate in accordance with the requirements set forth in 466.214(a) and (b) of this subpart.
 - (1) If home IV drug therapy is planned to continue for a time past the date the PRO has indicated, the physician or health care facility must request PRO review no less than 3 working days before the expiration of the current PRO approval.
 - (2) The PRO follows the process outline in 466.214(c).
 - (3) The PRO must complete subsequent reviews within 3 working days for the request.
 - (i) In this timeframe, the PRO must give the health care facility, if applicable, and physician an opportunity to discuss the case as described in 466.214.
 - (ii) If the health care facility and physician do not take advantage of the opportunity to discuss with the tie allowed, the PRO may make its determination based upon the information in its possession.
- (d) Prior review of change in drug. When the referring physician proposes a change to the IV drug therapy, the referring physician or the health care facility will request PRO approval of the revision in therapy within one working day of initiation of the change.
 - (1) The referring physician or health care facility must request PRO review in accordance with PRO-issued instruction.
 - (2) The PRO will follow the review process outlined in 466.214(c).
 - (3) The PRO will complete its review within three working days of the request.
 - (i) In this timeframe, the PRO must afford the health care facility and referring physician an opportunity to discuss the case as described in 466.214.
 - (ii) If the health care facility and referring physician do not take advantage of the opportunity to discuss the case within the time allowed, the PRO will make its determination based upon the information in its possession.
- (e) Retrospective reviews. For retrospective reviews, the PRO must adhere to the timing of review

requirements found in its contract with HCFA.

Notification—

- (a) The PRO must, within the timeframes given in 466.216, provide notification if its determination as follows:
 - (1) The PRO notifies the health care facility and referring physician by telephone as to whether it has determined that:
 - (i) Services are reasonable, appropriate, and medically necessary. The PRO issues an approval number and informs the health care facility, if applicable, and referring physician of the date by which review and subsequent approval must be requested for continuation of the IV drug therapy;
 - (ii) Services are not reasonable, appropriate, or medically necessary;
 - (iii) Services are medically necessary but neither the patient nor caregiver meets the selection criteria; or
 - (iv) The patient should receive the services if another setting.
 - (2) If the PRO does not authorize the services because they are not reasonable, appropriate and medically necessary in the home setting, within 1 working day of the determination it must, in accordance with the requirements of section 466.94(c), notify in writing:
 - (i) The beneficiary;
 - (ii) The referring physician;
 - (iii) The health care facility, and
 - (iv) The fiscal intermediary.
- (b) If the PRO determines that the services do not meet professionally recognized standards of care, the PRO will notify the referring physician and health care facility in accordance with the quality intervention plan in the PRO's contract.

Retrospective Reviews—

- (a) Random sampling. The PRO must periodically review a sample of cases to determine that the home IV therapy services meet professionally recognized standards of care and that the conditions in 466.214 are met.
- (b) Retrospective review of unapproved cases. On a retrospective, prepayment (and on an exception basis, postpayment) basis, the PRO reviews (upon the request of the physician or health care facility) any claims for the home IV drug therapy services for which PRO review was required but never completed and makes a determination in accordance with 466.214.
- (c) Validation reviews. The PRO in the State where the home IV drug therapy provider is located must

conduct a validation review of a sample of cases in which approval for home IV drug therapy services under this subpart was granted by telephone tier the PRO considered medical information by telephone but did not review actual medical records.

- (1) The PRO must be assured that information provided to the PRO was accurate and that the home IV drug therapy services met professionally recognized standards of care.
- (2) If inaccurate information was given to the PRO, the PRO must deny payment for the services if they are found to be uncovered based upon the correct information.
- (3) As a result of this review, the PRO may decide that future medical information must be submitted in writing.

Liability and Sanctions for Unreviewed Cases—

- (a) Payment contingent upon approval. No payment will be paid for any claim where the PRO has not approved the services for payment.
- (b) Failure of PRO to complete review. If, because of a PRO administrative error, the review is not completed within the timeframes outlined in 466.216, the PRO still must complete the review and issue an approval number or a notice denying the services.
- (c) Financial liability. Financial liability is determined in accordance with provisions of sections 1842(1) and 1879 of the Act and 405.330 through 405.336 of this chapter.
- (d) Corrective action.
 - (1) If the review is not completed timely, whether or not the PRO determines that the home IV drug therapy is appropriate and the physician or health care facility (or both) are the cause of the problem (including failure to make the request on a timely basis), the PRO must take whatever corrective actions are necessary to ensure that future cases are reported to the PRO for review within the outlined timeframes.
 - (2) If the information given over the telephone is found to be inaccurate or misleading, the PRO may take appropriate corrective actions.
- (2) Review of home intravenous drug therapy services before the initiation of or during the period in which the beneficiary is still receiving the services.

Time Limits for Issuance of the Reconsidered Determination—

- (a) Beneficiaries. If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits:

- (1) Within 3 working days after the PRO receives the request for reconsideration if:

- (i) The beneficiary is still An inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or
- (ii) The initial determination relates to home intravenous drug therapy services for which approval was denied and a request was submitted timely for an expedited reconsideration.

- (3) Within 30 working days after the PRO receives the request for reconsideration if:

- (i) The initial determination concerns ambulatory or noninstitutional services;
- (ii) The beneficiary is no longer an inpatient in a hospital or SNF [skilled nursing facility] for the stay in question or no longer receives home intravenous drug therapy services for which the PRO issued a denial determination; or
- (iii) The beneficiary does not submit a request for expedited reconsideration timely [sic].

Payment for Home Intravenous Drug Therapy Services (54 F.R. 46938)

This proposed rule sets forth the methodology for payment for home IV drug therapy services. This proposal would implement the provisions of section 1834(d) of the Social Security Act as added by section 203(c)(1) of the Medicare Catastrophic Coverage Act of 1988. Coverage of and payment for home IV drug therapy services under Part B of Medicare would be implemented on January 1, 1990.

Basis and Scope

- (a) Statutory basis. This subpart is based on sections 1834(d)(1) and (2) of the Act which, respectively:

- (1) Provide that payment for home IV drug therapy services is the lesser of the actual charges or a fee schedule amount; and
- (2) Require the Secretary to establish by regulation a per diem fee schedule for those services.

Reconsiderations and Appeals Reconsiderations and appeals are available under **part 473 of this chapter** for all PRO initial denial determinations.

Location for Submitting Requests for Reconsideration—

- (c) Expedited reconsideration. A request for an expedited reconsideration must be submitted directly to the PRO if the denial is a result of:
 - (1) Preadmission/preprocedure review; or

- (b) **Scope.** This subpart sets forth the methodology used to determine the per diem fee schedule amount for home IV drug therapy services, which are covered under Medicare beginning on January 1, 1990.

Determination of Amount Payable

- (a) **General rule.** Medicare payment for home IV drug therapy services, as defined in section 410.203 of this chapter, is made at 100 percent of the lesser of:
- (1) The actual charge; or
 - (2) The applicable per diem fee schedule amount and any applicable additional allowances determined under this subpart.
- (b) Separate fee schedules. Two separate fee schedule amounts are calculated; one for pain management drug therapy and one for antibiotic and other drug therapies.
- (c) Basis for calculating fee schedule amounts. The applicable fee schedule amount for each type of drug therapy is the per diem allowance for each of the home IV drug therapy service components plus, as appropriate, additional allowances applicable in special circumstances.
- (d) Service components. HCFA calculates a per diem fee schedule allowance for each of the following:
- (1) Pharmacy services.
 - (2) Pharmacy supplies.
 - (3) Pharmacy delivery.
 - (4) Nursing services and supplies.
 - (5) Other equipment.
- (e) Special circumstances. HCFA calculates additional allowances for each of the following:
- (1) Patient education and counseling at the time IV drug therapy begins in the home
 - (2) Multiple IV drug regimen.
 - (3) New drug introduced into existing drug regimen.

Calculation of Per Diem Fee Schedule Allowances for Calendar Year 1990

- (a) Pharmacy services.
- (1) An average hourly pharmacy rate is calculated by weighting an average hourly pharmacist rate based on direct and indirect costs and an average hourly pharmacy technician rate based on direct and indirect costs by the estimated time spent by each in drug preparation.
 - (2) A per dose cost of preparation is calculated for each type of drug by multiplying the average time spent in preparing the drug and evaluating patient outcome by the average hourly pharmacy rate.

- (3) A per diem cost of preparation is calculated for each type of drug by multiplying the per dose cost for the drug by the average number of doses per day.
- (4) The per diem allowance for pharmacy services for each type of drug therapy is equal to the per diem cost of preparing that type of drug.

(b) Pharmacy supplies.

- (1) A per dose cost of pharmacy supplies for each type of drug therapy is calculated by adding the cost of all supplies needed for that type of therapy.
- (2) A per diem cost of pharmacy supplies for each type of drug therapy is calculated by multiplying the per dose cost by the average number of doses per day.
- (3) The per diem allowance for pharmacy supplies for each type of drug therapy is equal to the per diem cost for supplies for that type of drug therapy.

(c) Pharmacy delivery.

- (1) A per trip nonlabor cost of delivery of drugs is calculated by multiplying the estimated average mileage per trip by the Federal mileage allowance divided by the estimated average number of deliveries per trip.
- (2) A per trip labor cost of delivery of drug is calculated by multiplying the estimated average travel time for each delivery by an average hourly salary rate for a delivery person based on direct and indirect costs.
- (3) A per diem cost of delivery for each type of drug is calculated by adding the per trip nonlabor and labor costs and multiplying the result by the estimated number of trips per day for each type of drug.
- (4) The per diem allowance for pharmacy delivery for each type of drug therapy is equal to the per diem cost of delivery for that type of drug therapy.

(d) Nursing services and supplies.

- (1) A per visit cost for patient care time is calculated by multiplying the average number of hours spent with a patient in each visit by the average hourly salary for a nurse based on direct and indirect costs.
- (2) A per visit cost for travel time is calculated by multiplying the average travel time per patient by the average hourly salary for a nurse based on direct and indirect costs.
- (3) The per visit costs calculated in paragraphs (d)(1) and (d)(2) of this section are adjusted for area differences in wage levels by a factor (established by HCFA) reflecting the relative home health agency wage level in the geo-

graphic area of the home IV drug therapy provider compared to the nation average home health agency wage level.

- (4) A per visit cost for travel is calculated by multiplying the estimated average mileage per visit by the Federal mileage allowance.
- (5) A per visit cost of nursing supplies is calculated by adding the cost of supplies used in each visit.
- (6) The per diem allowance for nursing services is calculated by adding the separate adjusted per visit cost for direct patient care **time** and travel time and the per visit costs for travel and nursing supplies and dividing by the average number of days between visits.
- (e) Other equipment. The per diem allowance for other equipment is the separate per diem cost of the equipment not related to either pharmacy or nursing services calculated for each type of drug therapy by dividing the cost of the equipment necessary for the therapy by the average useful life of the equipment.

[Proposed actual amounts for all above services for 1990 were \$45.44 per day for antibiotic therapy and \$31.63 per day for pain management therapy.]

Calculation of Additional Allowances for Calendar Year 1990

- (a) Patient education and counseling at the time IV drug therapy begins in the **home**. The amount of the allowance depends on whether the patient had begun IV drug therapy as a hospital inpatient.
 - (1) **Patient begins IV drug therapy while a hospital inpatient.** If the patient begins IV drug therapy as a hospital inpatient, the allowance is equal to two times the per visit cost for nursing services as a calculation by adding the per visit costs determined in 414.588 (d)(1) through (d)(4).
 - (2) Patient begins IV drug therapy outside the **hospital inpatient setting**. If the patient begins IV drug therapy in any setting other than that of a hospital inpatient, the allowance is equal to three times the per visit cost for nursing services as calculated by adding the per visit costs determined in 414.558 (d)(1) through (d)(4).
- (b) Multiple IV drug regimen. A per diem allowance is made for the additional pharmacy services and supplies, nursing services, and other equipment needed for a patient who receives concurrently more than one IV drug. The per diem allowance is equal to the sum of the following:

- (1) 50 percent of the applicable per diem allowance for pharmacy services as calculated in 414.558(a).
- (2) 100 percent of the applicable per diem allowance for pharmacy supplies as calculated in 414.558(b).
- (3) 100 percent of the applicable per diem allowance for other equipment & calculated in 414.558(e).
- (c) Nursing services for initial dose of new drug **introduced into the drug regimen:**
 - (1) **Applicability. This allowance** is made for nursing services related to one nursing visit for the initial dose when a prescription change introduces an additional covered home IV drug to the patient's drug regimen or substitutes a new covered home IV drug for one already being used.
 - (2) Amount. This allowance is equal to 50 percent of the per visit costs for nursing services as calculated by adding the per visit costs determined in section 414.558 (d)(1) through (d)(4).

Calculation of Per Diem Fee Schedule and Additional Allowances for Calendar Years After 1990

The **per diem** fee schedule and additional allowances for calendar years after 1990 are periodically recalculated to take into account increases in costs of nursing and pharmacy services, supplies, and delivery, and other equipment.

Conditions of Participation for Home Intravenous Drug Therapy Providers (54 F.R. 37220)

This proposed rule sets forth the conditions of participation that an entity would be required to meet in order to qualify as a home intravenous drug therapy provider. This proposal would implement the provisions of section 1861 (jj)(3) of the Social Security Act, which was added by section 203(b) of the Medicare Catastrophic Coverage Act of 1988. An entity that meets these conditions of participation would be eligible for payment from Medicare for covered home IV drug therapy services furnished to Medicare beneficiaries.

Basis and Scope

This subpart sets forth the conditions that entities must meet to be approved for participation in Medicare as home IV drug therapy providers under section 1861(jj) of the Act and part 489 of this chapter.

Definitions

As used in this subpart unless the context indicates otherwise, “home intravenous (IV) drug therapy provider,” “home IV provider” or “provider” means an entity that:

- (a) Incapable of providing covered home IV drugs, nursing and pharmacy services, and other services as are necessary for the administration of home IV drug therapy; and
- (b) Meets all the requirements of this subpart.

Condition of Participation; Compliance With Federal, State, and Local Laws

The home IV provider and all personnel who furnish services must be in compliance with applicable Federal, State, and local laws and regulations.

- (a) **Standard: Compliance with Federal laws.** The home IV provider must be in compliance with applicable Federal laws related to the health and safety of patients.
- (b) **Standard: Licensure of home IV provider.** If State or local law requires licensing, the home IV provider must be currently licensed or approved as meeting the standards established for licensure.
- (c) **Standard: Licensure of personnel.** Personnel who provide services, including individuals who provide services under arrangements with the home IV provider, must be licensed, registered, certified, or meet other applicable standards in accordance with applicable State and local laws.

Condition of Participation: Governing Body and Administration

- (a) **Standard: Governing body.** A home IV provider must have either:
 - (1) A governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing all operations of the home IV provider; or
 - (2) Individuals who are legally responsible for the conduct of the home IV provider and who carry out the governing body functions that are specified in this section.
- (b) **Standard: Disclosure of ownership.** The home IV provider must comply with the provisions of subpart C of part 420 of this chapter, which require health care providers and fiscal agents to disclose certain information about ownership and control.
- (c) **Miscellaneous reporting.** The home IV provider must furnish information relevant to, and participate in, surveys and studies concerning cost-

findings or other issues relating to the efficient administration of the home IV therapy benefit as requested by the Secretary under section 1861(jj)(3)(x) of the Act.

- (d) **Standard: Chief executive officer.** The governing body must appoint a chief executive officer who meets the following conditions:
 - (1) Assumes responsibility for the overall management of the facility under the authority delegated by the governing body.
 - (2) Assumes responsibility for the day-to-day operation of the home IV provider.
- (e) **Standard: Patient care policies.** The home IV provider must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:
 - (1) A description of the services furnished by the home IV provider’s employees and those furnished under arrangements.
 - (2) The diagnostic criteria that identify the patients for whom the services are designed.
 - (3) Provisions for accepting only those patients whose needs can be met by the services it furnishes.
 - (4) Procedures for the acceptance of a referral, including the assignment of appropriate staff to conduct a timely assessment of the patient’s medical and psychological readiness for home IV drug therapy services.
 - (5) Procedures for quickly notifying the referring physician if the patient does not meet the home IV provider’s admission criteria.
 - (6) Procedures for notifying the referring physician of incidence of phlebitis, IV infiltration, or site infection that occurs after the provider begins furnishing home IV drug therapy services.
- (f) **Standard: Contracted services and professional management responsibility.**
 - (1) The home IV provider must:
 - (i) Retain professional and administrative responsibility for and control and supervision of contracted services; and
 - (ii) Ensure that the services are furnished:
 - (A) In a safe and effective manner by nurses or pharmacists meeting the qualifications of this subpart; and
 - (B) In accordance with the patient’s plan of care and other applicable requirements of this subpart.
 - (2) With each contractor that provides arranged services, the home IV provider must have a legally binding written agreement that meets at least the following requirements:
 - (i) Identifies the services to be provided.

- (ii) Specifies that contracted services are provided only if directly authorized by the home IV provider.
- (iii) Describes the manner in which the contracted services are coordinated, supervised, and evaluated by the home IV provider.
- (iv) Delineates the roles of the home IV provider and the contractor in the patient care process.
- (v) Provides for the preparation of patient records with progress notes and observations and for the prompt incorporation of the patient records into the clinical record of the home IV provider.
- (vi) Provides that the requirements for the services furnished under arrangements and personnel who furnish them are the same as for the services furnished directly by the home IV provider and the personnel who furnish them.
- (vii) Specifies the financial arrangements that provide for payment to the contractor by the home IV provider for the provision of covered services.
- (viii) Specifies that a contractor that furnishes services under arrangements may not bill the patient or Medicare for covered services.

Condition of Participation: Patient Selection

After a patient's referring physician requests home IV drug therapy, the home provider makes an assessment of each patient and his or her needs. For hospital inpatients, the home IV provider must make this assessment prior to discharge. The home IV provider furnishes services only to patients whose needs can be met by its services.

- (a) Standard: Medical criteria. A patient must:
 - (1) Be under the care of a licensed referring physician who either prescribed the home IV drug or established the plan of care, or both, and who continually monitors the home IV drug therapy;
 - (2) Have a clinical status that allows IV drugs to be safely administered in the home;
 - (3) Have venous sites available for peripheral IV catheter or needle placement or have a central venous catheter or other central venous access device; and
 - (4) Be unable, for medical or therapeutic reasons, to take the provided medication orally or by other means less intrusive than IV.
- (b) Standard: Nonmedical criteria. A patient must:
 - (1) Be capable of performing safely self-administration of drugs and self care after

adequate patient education (for example, be able to learn aseptic technique and heparin lock maintenance and read and understand the labeling of the home IV drugs) or have a primary care giver who can perform these tasks;

- (2) Be motivated to use home IV drug therapy services;
- (3) Be psychologically stable (that is, the prospect for adherence to a disciplined medical regimen is realistic); and
- (4) Have a home environment that is conducive to the provision of home IV drug therapy services (that is, a clean home with electricity, a telephone, running water, refrigeration, and enough space to support home IV drug therapy services).

Condition of Participation: Plan of Care

For each patient, the referring physician must establish and periodically review a plan of care.

- (a) Standard: Development of the plan of care. A plan of care must meet the following requirements:
 - (1) The **plan** of care is developed by the patient's referring physician.
 - (2) The plan of care is implemented by the home IV provider.
 - (3) The plan of care is based on the referring physician's initial and ongoing individual patient assessments.
 - (4) The plan of care is reviewed by the referring physician as necessary, but at least once every 30 days.
 - (5) The plan of care includes at least the following current information about the patient and the home IV drug therapy services to be provided:
 - (i) **The patient's name, gender, age, and lean body weight.**
 - (ii) **A narrative description of the appropriate diagnoses.**
 - (iii) **The patient's drug allergies or sensitivities.**
 - (iv) **The patient's current drug therapy, including nonprescription drugs, and home remedies.**
 - (v) **The goal of the provision of home IV drug therapy services for the patient.**
 - (vi) **The drugs and method of drug therapy administration to be furnished by the home IV provider including:**
 - (A) **Amount** of dosage and timing of administration;
 - (B) **Route** of administration, either peripheral or central venous line.
 - (c) **Frequency** of IV site monitoring; and
 - (D) **Type** of IV equipment, related sup-

plies and other equipment, and fluids to be administered.

(vii) Identifying physician information, the physician's signature, and the date.

- (b) **Standard: Referring physician review of plan or care.** The referring physician review of the plan of care must meet the following requirements:
- (1) The referring physician reviews the patient's process in attaining the objectives of the plan of care at least every 30 days.
 - (2) The review is based upon appropriate information provided by health professionals, including information furnished by the registered nurse and pharmacist employed by the home IV provider.

Condition of Participation: Central Clinical Records

In accordance with accepted principles of practice, the home IV provider must establish and maintain a clinical record for all individuals receiving care and services including those who are not entitled to Medicare. Each clinical record must be completely, promptly, and accurately documented, readily accessible, and systematically organized to ease retrieval and compilation of information.

- (a) **Standard: Content.** Each clinical record is a comprehensive compilation of information of medical and other data that must contain sufficient information to identify the patient clearly and to justify the diagnosis treatment. Entries in the clinical record must be made for all services provided directly or under arrangements. Entries must be made for each treatment performed and must be signed by the individual who performs the services. Documentation on each patient must be consolidated into one clinical record that must contain the following information:
- (1) Patient identification data.
 - (2) The initial patient assessment and subsequent reassessments.
 - (3) Current plan of treatment.
 - (4) Consent and authorization forms.
 - (5) Past and present pertinent medical history.
 - (6) Complete documentation of all services provided.
 - (7) Upon completion of treatment, a summary that includes a description of patient status relative to goal achievement, prognosis, and future treatment considerations.
- (b) **Standard: Retention and preservation.** The home IV provider must retain clinical records for the appropriate time period as specified in this paragraph. If the requirements of State law are used to define the time period for maintaining

clinical records, it must be the law of the State in which the services were provided to the patient.

- (1) If the State where the services are furnished has a law that applies to the provider governing the maintenance of clinical records, the home IV provider must maintain its clinical records for the time required by that law.
 - (2) In the absence of an applicable State law, the home IV provider must maintain clinical records for the time periods provided under the appropriate statute of limitations concerning medical malpractice in the State.
 - (3) If there is no applicable State law or State statute of limitations concerning medical malpractice, the home IV provider must maintain clinical records for at least 5 years.
 - (4) In addition, for services furnished to a minor, the home IV provider must maintain clinical records for at least 3 years after the individual attains the age of majority under State law.
- (c) **Standard: Protection of information.** The home IV provider must-
- (1) Safeguard the clinical record against loss, destruction, or unauthorized use;
 - (2) Have procedures to govern the use and removal of records, to ensure release of information only to authorized individuals, and to ensure that unauthorized individuals cannot gain access to, or alter, patient records;
 - (3) Obtain the patient's written consent before releasing information not required to be released by law; and
 - (4) Release original records only in accordance with Federal or State Laws, court orders, or subpoenas.
- (d) **Standard: Patient access.** The home IV provider must permit each patient or his or her legal representative to inspect or obtain copies of his or her clinical records within 48 working hours after the provider receives a written request.

Condition of Participation Core Staff, Core Services, and Full-time Availability of Patient Core Services

A home IV provider must make all necessary nursing and pharmaceutical services available 24 hours a day, 7 days a week to meet the reasonable needs of its patients with respect to home IV drug therapy services.

- (a) **Standard: Core staffing requirements.** A home IV provider must employ directly either a full-time registered nurse or a full-time registered pharmacist.
- (b) **Core services.** A home IV provider must perform the following oversight and supervisory functions itself (that is, these functions may not be furnished under arrangements);

- (1) Assurance that all patient care related nursing and pharmacy services, whether furnished directly or under arrangements, are available on a 24-hour-a-day, 7-day-a-week basis.
 - (2) Development and coordination of all activities of nurses and pharmacists including assuring that only qualified, properly trained individuals furnish these services.
 - (3) Necessary consultations and coordination concerning a patient's plan of care with the patient's physician and provision of all patient laboratory test results.
 - (4) Conduction a quality assessment and assurance program including drug regime review.
- (c) **Standard: 24-hour availability of patient care services.**
- (1) To meet the needs of patients, a home IV provider may contract for additional nursing or pharmacy services to supplement the services directly furnished by the home IV provider. If services directly furnished under arrangement [sic], the provider must maintain professional, financial: and administrative responsibility for the services.
 - (2) A home IV provider must be able to meet the following time requirements related to care of a patient:
 - (i) The home IV provider must make routine or urgently needed nursing, pharmacy, and related services and home IV drugs and supplies available 24 hours a day, 7 days a week.
 - (ii) The home IV provider must be accessible to patients at all times. If a patient or caregiver telephones the home IV provider with a problem concerning the administration of a drug or malfunctioning equipment, the provider must be able to make telephone contact with the patient or caregiver within 10 minutes, and the provider must be able to resolve that problem as expeditiously as possible given the nature of the problem.
 - (iii) In an emergency, the provider must be able to deliver drugs to the patient at least 30 minutes before the drugs are scheduled for use.
 - (iv) The home IV provider must furnish services in a manner consistent with accepted standards of medical practice.

Condition of Participation: Nursing Services

- (a) **General requirements.** The home IV provider is responsible for furnishing nursing services, directly or under arrangements, that are necessary for the provision of IV drug therapy services. Persons

furnishing the nursing services either as employees of the home IV provider or of the organization under contract with the home IV provider must be either registered nurses, or in States that permit such practice, physicians or physicians assistants under the supervision of a physician. (In such States, the references in this subpart to a "registered nurse" or "nurse" are read to include physician assistants.) In addition, the home IV provider must:

- (1) Direct and staff nursing services to ensure that the needs of its patients are met;
- (2) Specify the patient care responsibilities of the nurses; and
- (3) Ensure that the requirements of paragraphs (b) through (d) of this section are met.

(b) **Education and experience.**

- (1) The home IV provider must ensure that each nurse who furnished home IV drug therapy services meets the following requirements for education, experience, and proficiency:
 - (i) Education in the principles and practices of infusion therapy and cardiopulmonary resuscitation.
 - (ii) Experience in patient assessment and infusion therapy.
 - (iii) Proficiency in all clinical aspects of IV therapy with validated competency in clinical judgment and practice demonstrated by work experiences. For example, each nurse must be able to access peripheral veins and must be able to recognize medication and solution incompatibilities.
 - (iv) Ability to perform the following procedures:
 - (A) **Interpret the physician's order for IV therapy and administer IV medications as ordered.**
 - (B) **Perform venipuncture and insertion of all types of needles and catheters commercially available (excluding the insertion of subclavian, jugular, and cut-down catheters).**
 - (C) **Prepare IV solutions with the addition of medications in the absence of admixture services.**
 - (D) **Initiate, monitor, and terminate IV solutions and additives.**
 - (E) **Evaluate the effectiveness of the dosage, frequency, and route of administration of IV drugs and the patient's adherence to the drug regimen.**
 - (F) **Set the flow rates established by the physician for all IV solutions and medications.**

- (G) Maintain and replace sites, tubing, and dressing in accordance with established policy.
 - (H) Draw blood.
 - (v) Thorough knowledge of and proficient technical ability in the use of the specific type of IV equipment **to** be used by a particular patient so **that the nurse is** able to evaluate IV equipment and identify when maintenance would be necessary.
 - (vi) Ability to observe and assess all significant reactions related to IV therapy and initiate appropriate nursing interventions.
- (c) Aseptic practices. Each nurse must follow established infection control and aseptic practices.
 - (d) Physician notification. All significant findings of the nurse in the course of delivering home IV services must be communicated to the physician.
 - (e) Documentation. Each nurse must document in the patient's clinical record his or her action associated with the preparation, administration, and termination of all aspects of IV therapy.

Condition of Participation: Pharmacy Services

The home IV provider must ensure that a registered pharmacist is responsible for purchasing, preparation, safe administration, and clinical monitoring of drugs. The home IV provider may directly furnish necessary pharmacy services or it may enter into arrangements for the services.

- (a) **Standard: Pharmacy services management.** The home IV provider must ensure that necessary pharmacy services, furnished directly or under arrangements, are furnished in accordance with the following requirements:
 - (1) The policies and procedures of the home IV provider must ensure that pharmacy practice at all times is consistent with applicable law and regulations governing professional licensure and operation of pharmacies.
 - (2) The home IV provider must maintain and make available an up-to-date copy of HCFA's list of covered home IV drugs and pharmaceutical references **that** include official pharmaceutical practice as it relates to patient care.
 - (3) The home IV provider must maintain patient profiles that include:
 - (i) The patient's name, age, and lean body weight;
 - (ii) The patient's diagnosis or diagnoses;
 - (iii) Clinical information relating to the patient's initial and ongoing home IV drug therapy;
 - (iv) Current drug therapy provided to the

- patient including nonprescription and home remedy products; and
 - (v) A description of the patient's drug allergies or sensitivities.
- (4) A pharmacist reviews each prescription order before dispensing a drug to ensure that the drug is a covered home IV drug and that the correct drug is dispensed to the patient.
 - (5) A pharmacist assists the physician in determining the appropriate schedule for monitoring the patient through laboratory testing. This schedule must include identification of tests to be performed and the Medicare-approved laboratory that will perform the tests and frequency of testing and obtaining the results.
 - (6) A pharmacist supervises support personnel to ensure adequate quality of the drugs and pharmaceutical supplies.
- (b) **Standard: Storage, equipment, and preparation area.**
 - (1) The IV provider must ensure that drugs, supplies, and equipment are maintained in the pharmacy in accordance with the following procedures:
 - (i) Drugs must be stored separately under proper conditions of sanitation, temperature, light, moisture, ventilation, and security.
 - (ii) Areas used in the preparation of sterile products must be constructed **to minimize** opportunities for particulate and microbial contaminations and must be separate from areas used in preparation of nonsterile products.
 - (iii) Work surfaces are kept free of equipment, supplies, records, and labels unrelated **to the** preparation of **a** given prescription.
 - (iv) Work surfaces and equipment must be disinfected **after** the preparation of each prescription.
 - (v) Clean work benches or laminar flow hoods **must be used in the preparation of IV drugs and must be inspected at least annually in accordance with standard inspection practice.**
 - (vi) **Both ingredients and final products must be inspected for the presence of inappropriate particulate matter or signs of deterioration or microbial contamination. The equipment necessary for such an inspection must be maintained by the pharmacy.**
 - (vii) Drugs must be kept in a locked storage area.
 - (vii) Each dosage unit of both a cytotoxic drug and a Schedule II controlled drug

- must be accounted for in a distribution log.
- (2) Unless contraindicated, an appropriate air-eliminating filter must be employed in the home for delivery of IV fluids.
- (3) Mislabeled or otherwise unusable drugs must not be made available for patient use.
- (4) Outdated drugs must be destroyed.
- (c) **Standard: Drug labeling.** The label on any IV drug or solution that has been dispensed to a patient must contain at least the following information:
 - (1) The name, address, and telephone number for the pharmacy and the telephone number of the home IV provider if the pharmacy services are furnished under arrangements.
 - (2) The dates of both preparation and expiration of the drug.
 - (3) The pharmacy's identifying serial number for the drug order or prescription.
 - (4) The full name of both the patient and prescribing physician.
 - (5) The name of the drug, its strength, and the amount dispensed.
 - (6) The directions for use including the scheduled date, time, and rate of administration, and appropriate space for the patient or caregiver to add the date and time the solution is started. These directions must indicate that the IV fluids must be completely used or discarded within 24 hours of mixing or unfreezing a mixture.
 - (7) The directions for storage.
 - (8) Cautionary or accessory labels if appropriate.
 - (9) The lot number or control number of the batch from which the drug was obtained.

Condition of Participation: Patient and Caregiver Evaluations and Instructions

To ensure safe home IV therapy for the patient, a registered nurse who is proficient in the delivery of home IV drug therapy services evaluates the patient to determine suitability for the provision of home IV drug therapy services. If the nurse determines that the patient is suitable for this therapy and the home IV provider can furnish the necessary therapy, the nurse trains the patient or caregiver or both, as appropriate, in providing the therapy and in proper maintenance of the equipment.

- (a) **Standard: Patient evaluation.** The registered nurse performs the following activities:
 - (1) Reviews the referring physician's medical orders before evaluating a patient for home IV drug therapy.
 - (2) Before accepting the patient for care, evaluates the patient or caregiver for general compe-

tency and specific comprehension of the particular IV drug therapeutic procedures to be used. In making this evaluation, the nurse:

- (i) Discusses possible complications of the treatment with the patient or caregiver or both as appropriate.
 - (ii) Explains and demonstrates home IV drug therapy procedures to the patient or caregiver.
 - (iii) After the patient or caregiver demonstrates IV drug therapy procedures, including aseptic techniques, evaluates and documents the competency and proficiency of the patient or caregiver.
- (3) May inspect the patient's home prior to hospital discharge to ascertain that there is an area in the home available for storage of drugs and supplies and an area available for use of sterile supplies.
- (4) Supervises the patient or caregiver when either starts the first infusion therapy at home to verify his or her ability to transfer learning from the provider setting to the home setting.
- (b) **Standard: Patient and caregiver education and instructions.** The nurse instructs the patient or caregiver, as appropriate, in home IV drug therapy procedures, including aseptic techniques and provides written and illustrated instructions.
 - (1) The written instructions that are prepared for each different drug class and administration route must include the following information:
 - (i) A step-by-step description of the procedures that the patient or caregiver must follow in administering an IV drug, including procedures for any probable emergency that might arise.
 - (ii) Storage procedures.
 - (iii) Procedures for disposal of drugs and IV equipment.
 - (iv) A telephone number that would enable a patient to receive assistance at any time.
 - (2) **The** nurse must instruct the patient or caregiver about the following:
 - “(i) Methods of detecting early signs and symptoms of IV-related sepsis and complications so that they may be reported immediately to the home IV provider's medical personnel.
 - (ii) When appropriate, use of electronic controlling devices (for example, an infusion pump) in delivery of home IV drug therapy so that the patient or caregiver can recognize any malfunction that should be reported to the home IV provider.
 - (iii) Emergency interventions for possible IV

- complications that can be performed by the patient or caregiver.
- (iv) Discarding IV needles in an appropriate receptacle (such as a Sharp's container) that is properly labeled and that is removed by the home IV provider staff or personnel at least every 3 days.
- (v) Procedures for recording the administration of IV solutions and drugs so the information can be given to the home IV provider and attached to the patient's clinical record.
- (3) The nurse must discuss the range of physical activity that is appropriate for the patient.

Condition of Participation: Protocols and Policies

The home IV provider adheres to the following procedures and has written protocols and policies consistent with respect to the provision of home IV drug therapy items and services.

- (a) **Standard: First dose.** The first dose of any drug not previously administered intravenously is administered under the direct supervision of a physician or nurse who must:
 - (1) remain in attendance for a time period sufficient to make sure that the patient is stable; and
 - (2) Have resuscitation medication and equipment to treat anaphylaxis readily available.
- (b) **Standard: Venipuncture and catheter care.**
 - (1) The site of a peripheral catheter is rotated by the nurse at least every 3 days. A catheter whose tip lies in a central vessel must be rotated by a physician when appropriate.
 - (2) IV administration sets are changed at least every 24 hours by the patient or caregiver.
 - (3) IV dressings should be changed at least every 48 hours or immediately upon becoming soiled or wet.
 - (4) The air elimination filter is routinely changed.
 - (5) The central line catheter site is inspected by a nurse at least once each week
 - (6) Aseptic techniques are practiced during all venipuncture, dressing changes, catheter care, and assembly of IV infusion systems.
- (c) **Standard: Quality of the air elimination filter and sterility of the catheter.**
 - (1) On a sample of patients, the nurse packages air elimination filters that have been removed by the nurse from the IV tubing and immediately sends them to an independent laboratory for analysis of particulate matter and bacterial and fungal contamination.
 - (2) On a sample basis, the home IV provider packages catheters that have been removed

from patients and immediately sends them to an independent laboratory for analysis of sterility.

- (3) The home IV provider keeps copies of laboratory results on the testing of both air elimination filters and catheters that are made available for review upon request.
- (d) **Standard: Drug therapy review.**
 - (1) The pharmacist and nurse must review the combination of IV drugs and equipment for appropriateness before drug therapy is initiated.
 - (2) The pharmacist must conduct ongoing review (at least once every 3 days) of the drug therapy and inform the physician of significant findings. As a minimum, this review must include the appropriateness of the drug regimen and any instances of therapeutic duplication of drugs.
- (e) **Standard: Patient rights and responsibilities.** The home IV provider must ensure that the following requirements are met:
 - (1) Treatment of a patient begins only if the home IV provider is capable of furnishing needed care at the level of intensity required by the condition of the patient.
 - (2) Each patient receives care appropriate to his or her needs in a timely manner.
 - (3) The patient is informed in a timely manner of the need for transfer to another medical entity or level of care and of any appropriate alternatives.
 - (4) If the home IV drug therapy is to end without transfer to another medical entity, the patient is informed in a timely manner of the impending discharge, continuing care requirements and other available services, if needed.
 - (5) Patients' rights as set forth in this paragraph are honored and patients are informed of their responsibilities, if any, in the care process. The rights and responsibilities are clearly stated in documents distributed to patients upon admission to the home IV drug therapy program.
 - (6) Procedures are established to deal with patient grievances and patient-recommended changes without coercion, discrimination, reprisal, or interruption of services. A patient is informed at the beginning of home IV drug therapy about these procedures for making, reviewing, and resolving complaints.
- (f) **Standard: Written protocols and policies.** The home IV provider has written protocols and policies that are consistent with these procedures.

Condition of Participation: Quality Assurance

The home IV provider maintains an ongoing quality assurance program designed to monitor patient care objectively and systematically, evaluate the quality and appropriateness of patient care, resolve identified problems, and pursue other opportunities to improve patient care, resolve identified problems, and pursue other opportunities to improve patient care.

- (a) **Standard: Program objectives.** Through an ongoing, planned, and systematic process, the home IV provider monitors and evaluates the quality and appropriateness of patient care, including the performance of employees and other personnel who furnish services under arrangements with the home IV provider. The home IV provider includes at least the following in a written evaluation plan:
 - (1) Scope and objectives of the quality assurance activities.
 - (2) Activities identified for monitoring and evaluation.
 - (3) Methods for implementing the monitoring and evaluation activities and for reporting the results.
 - (4) Mechanisms for taking follow-up action.
 - (5) Staff responsibilities for each activity in the quality assurance program.
- (b) **Standard: Patient care.**
 - (1) The monitoring and evaluation of the quality and appropriateness of patient care by the home IV provider must include identification of important aspects of care or service and focus on high-risk high-volume, or problem-prone activities.
 - (2) The home IV provider collects data about the following matters:
 - (i) Length of home IV drug therapy by diagnosis and treatment.
 - (ii) Incidence and causes of patient rehospitalization.
 - (iii) Incidence of:
 - (A) Phlebitis;

- (B) Infiltration;
 - (C) Site infection; and
 - (D) Other infection.
- (iv) Hydration and nutritional status.
- (3) The home IV provider analyzes the data it collects at least annually to determine the frequency of negative outcomes and prescribes corrective action for negative outcomes.
- (c) **Standard: Service delivery.** The provider determines the following:
 - (1) Drugs and IV equipment were delivered timely to the patient.
 - (2) The patient could read the preparation and expiration dates on the drug labels.
 - (3) A nurse visited a patient with a peripheral IV catheter placement every 3 days and rotated the peripheral IV injection site.
 - (4) A nurse visited any patient with a central line at appropriate intervals for monitoring.
 - (5) Procedures have been established to enable patients to make complaints.
 - (6) The provider found acceptable solutions for complaints and kept a record of both.

Condition of Participation: Infection Control

The home IV provider must develop infection control procedures. These procedures must address at least staff personal hygiene and health status, isolation precautions, aseptic procedures, cleaning and sterilization of equipment, and methods to avoid transmitting infections. The home IV provider:

- (a) Advises staff, patients, and caregivers of any necessary precautions, including infection control and personal hygiene and their responsibilities in the infection control program; and
- (b) Develops a system for evaluating, reporting, and maintaining records of infection related to the care of service provided among patients and as appropriate, among staff.