CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 170	**Date: May 10, 2013**
	Change Request 8275

SUBJECT: Updates to Medicare Coverage of Hepatitis B Vaccine and its Administration and Medicare Coverage of the Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (PPPS)

I. SUMMARY OF CHANGES: This change request serves to make the Medicare Benefit Policy Manual provisions consistent with modified regulatory requirements.

EFFECTIVE DATE: January 1, 2012 - Medicare Coverage of the Annual Wellness Visit (AWV); January 1, 2013 - Medicare Covergage of Hepatitis B Vaccine
IMPLEMENTATION DATE: June 10, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/Table of Contents
R	15/50.4.4.1/Antigens
R	15/50.4.4.2/Immunizations
R	15/280.5/Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (PPPS)
R	16/90/Routine Services and Appliances

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-02	Transmittal: 170	Date: May 10, 2013	Change Request: 8275

SUBJECT: Updates to Medicare Coverage of Hepatitis B Vaccine and its Administration and Medicare Coverage of the Annual Wellness Visit (AWV) Providing Personalized Prevention Plan Services (PPPS)

EFFECTIVE DATE: January 1, 2012 - Medicare Coverage of the Annual Wellness Visit (AWV); January 1, 2013 - Medicare Covergage of Hepatitis B Vaccine
IMPLEMENTATION DATE: June 10, 2013

I. GENERAL INFORMATION

A. Background: Section 1861(s)(10)(B) the Social Security Act (the Act) authorizes Medicare coverage of "hepatitis B vaccine and its administration," if furnished to an individual who is at high or intermediate risk of contracting hepatitis B. Implementing regulations were established at 42 CFR 410.63. The regulations were modified in 2012 to add "persons diagnosed with diabetes mellitus" under the high risk group category for coverage under this benefit.

Sections 1861(s)(2)(FF) and 1861(hhh) of the Act authorize Medicare coverage of an AWV providing PPPS. Implementing regulations are established at 42 CFR 410.15. The regulations were modified in 2011 to incorporate a health risk assessment (HRA) in the provision of PPPS during the AWV.

B. Policy: This change request serves to make the Medicare Benefit Policy Manual provisions consistent with modified regulatory requirements.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8275.1	Contractors should be aware of the instructions in Pub. 100-02, chapter 15, section 50.4.4.2 has been updated to include persons diagnosed with diabetes mellitus to the high risk group category consistent with 42 CFR section 410.63. Note all other aspects of this section remain the same.	X	X		X	X						
8275.2	Contractors should be aware of the instructions in Pub. 100-02, Chapter 15, section 280.5 has been updated to include HRA provisions consistent with 42 CFR section 410.15. Note all other aspects of this section remain the same.	X	X		X	X						

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
8275.3	Contractors should be aware of the instructions in Pub. 100-02, Chapter 16, section 90 has been updated to align with 42 CFR section 411.15(a)(1), which identifies the exceptions to the coverage exclusion for routine physical checkups. Note all other aspects of this section remain the same.	X	X		X	X						
8275.4	Contractors should be aware of the instructions in Pub. 100-02, Chapter 15, section 50.4.4.1 has been updated to align with Chapter 16, section, 90 which identifies a reasonable supply of antigens is considered to be not more than a 12-week supply of antigens that has been prepared for a particular patient at any one time. Note all other aspects of this section remain the same.	X	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
	None							

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage and Analysis) , Cheryl Gilbreath, 410-786-5919 or Cheryl.Gilbreath@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage and Analysis)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

Section B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Benefit Policy Manual
Chapter 15 – Covered Medical and Other Health Services

Table of Contents

(Rev. 170, Issued: 05-10-13)

280.5 – Annual Wellness Visit (AWV) *Providing* Personalized Prevention Plan Services (PPPS)

50.4.4.1 - Antigens

(Rev. 170, Issued: 05-10-13, Effective: 01-01-12, Medicare Coverage of the Annual Wellness Visit (AWV); 01-01-13- Medicare Coverage of Hepatitis B Vaccine, Implementation: 06-10-13)

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-week supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

50.4.4.2 – Immunizations

(Rev. 170, Issued: 05-10-13, Effective: 01-01-12, Medicare Coverage of the Annual Wellness Visit (AWV); 01-01-13- Medicare Coverage of Hepatitis B Vaccine, Implementation: 06-10-13)

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

A. Pneumococcal Pneumonia Vaccinations

Effective for services furnished on or after May 1, 1981, the Medicare Part B program covers pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. This includes revaccination of patients at highest risk of pneumococcal infection. Typically, these vaccines are administered once in a lifetime except for persons at highest risk. Effective July 1, 2000, Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

An initial vaccine may be administered only to persons at high risk (see below) of pneumococcal disease. Revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years have [passed since the previous dose of pneumococcal vaccine.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. It is not appropriate for routine revaccination of people age 65 or older that are not at highest risk.

Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about his or her vaccination history in the past 5 years, the vaccine should be given. However, if the patient is certain he/she was were vaccinated in the last 5 years, the vaccine should not be given. If the patient is certain that the vaccine was given more than 5 years ago, revaccination is covered only if the patient is at high risk.

B. Hepatitis B Vaccine

Effective for services furnished on or after September 1, 1984, P.L. 98-369 provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. This coverage is effective for services furnished on or after September 1, 1984. High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;
- Clients of institutions for the mentally retarded;

- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men;
- Illicit injectable drug abusers*; and*
- *Persons diagnosed with diabetes mellitus.*

Intermediate risk groups currently identified include:

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

EXCEPTION: Persons in both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy, by a doctor of medicine or osteopathy, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians' services provision of law.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

C. Influenza Virus Vaccine

Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Typically, these vaccines are administered once a flu season. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

280.5 – Annual Wellness Visit (AWV) *Providing* Personalized Prevention Plan Services (PPPS)

(Rev. 170, Issued: 05-10-13, Effective: 01-01-12, Medicare Coverage of the Annual Wellness Visit (AWV); 01-01-13- Medicare Coverage of Hepatitis B Vaccine, Implementation: 06-10-13)

A. General

Pursuant to section 4103 of the Affordable Care Act of 2010 (the ACA), the Centers for Medicare & Medicaid Services (CMS) amended section 42 CFR 411.15(a)(1) and 42 CFR 411.15(k)(15) (list of examples of routine physical examinations excluded from coverage), effective for services furnished on or after January 1, 2011. This expanded coverage, as established at 42 CFR 410.15, is subject to certain eligibility and other limitations that allow payment for an annual wellness visit (AWV) *providing* personalized prevention plan services (PPPS), when performed by *a* health professional *(as defined in this section)*, for an individual who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period, and has not received either an initial preventive physical examination (IPPE) or an AWV within the past 12 months. Medicare coinsurance and Part B deductibles do not apply.

The AWV will include the establishment of, or update to, the individual's medical/family history, measurement of his/her height, weight, body-mass index (BMI) or waist circumference, and blood pressure (BP), with the goal of health promotion and disease detection and encouraging patients to obtain the screening and preventive services that may already be covered and paid for under Medicare Part B. Definitions relative to the AWV are included below.

Coverage is available for an AWV that meets the following requirements:

1. It is performed by a health professional; and,

2. It is furnished to an eligible beneficiary who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period, and he/she has not received either an IPPE or an AWV providing PPPS within the past 12 months.

Sections 4103 and 4104 of the ACA also provide for a waiver of the Medicare coinsurance and Part B deductible requirements for an AWV effective for services furnished on or after January 1, 2011.

B. Definitions Relative to the AWV:

Detection of any cognitive impairment: The assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient reports, concerns raised by family members, friends, caretakers, or others.

Eligible beneficiary: An individual who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period and who has not received either an IPPE or an AWV providing PPPS within the past 12 months.

Establishment of, or an update to, the individual's medical/family history: At a minimum, the collection and documentation of the following:

a. Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

b. Use or exposure to medications and supplements, including calcium and vitamins.

c. Medical events in the beneficiary's parents and any siblings and children, including diseases that may be hereditary or place the individual at increased risk.

First AWV providing PPPS: The provision of the following services to an eligible beneficiary by a health professional *that include, and take into account the results of, a health risk assessment* as those terms are defined in this section:

a. Review (and administration if needed) of a health risk assessment (as defined in this section).

b. Establishment of an individual's medical/family history.

c. Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

d. Measurement of an individual's height, weight, BMI (or waist circumference, if appropriate), BP, and other routine measurements as deemed appropriate, based on the beneficiary's medical/family history.

e. Detection of any cognitive impairment that the individual may have as defined in this section.

f. Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

g. Review of the individual's functional ability and level of safety based on direct observation, or the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available

screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

h. Establishment of the following:

(1) A written screening schedule for the individual, such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP), *and the individual's health risk assessment (as that term is defined in this section),* the individual's health status, screening history, and age-appropriate preventive services covered by Medicare.

(2) A list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE, and a list of treatment options and their associated risks and benefits.

i. Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

j. Any other element determined appropriate through the National Coverage Determination (NCD) process.

Health professional:

a. A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Social Security Act (the Act); or,

b. A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or,

c. A medical professional (including a health educator, registered dietitian, or nutrition professional or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in 42CFR 410.32(b)(3)(ii)) of a physician as defined in this section.

Health Risk Assessment *means, for the purposes of the annual wellness visit, an evaluation tool that meets the following criteria:*

a. collects self-reported information about the beneficiary.

b. can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.

c. is appropriately tailored to and takes into account the communication needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

d. takes no more than 20 minutes to complete.

e. addresses, at a minimum, the following topics:

1. demographic data, including but not limited to age, gender, race, and ethnicity.

2. self assessment of health status, frailty, and physical functioning.

3. psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue.

4. Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.

5. Activities of daily living (ADLs), including but not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

6. Instrumental activities of daily living (IADLs), including but not limited to, shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

Review of the individual's functional ability and level of safety: At a minimum, includes assessment of the following topics:

a. Hearing impairment,

b. Ability to successfully perform activities of daily living,

c. Fall risk, and,

d. Home safety.

Subsequent AWV providing PPPS: The provision of the following services to an eligible beneficiary by a health professional *that include, and take into account the results of an updated health risk assessment,* as those terms are defined in this section:

a. Review (and administration if needed) of an updated health risk assessment (as defined in this section).

b. An update of the individual's medical/family history.

c. An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual, as that list was developed for the first AWV providing PPPS *or the previous subsequent AWV providing PPPS.*

d. Measurement of an individual's weight (or waist circumference), BP, and other routine measurements as deemed appropriate, based on the individual's medical/family history.

e. Detection of any cognitive impairment that the individual may have as defined in this section.

f. An update to the following:

(1) The written screening schedule for the individual as that schedule is defined in this section, that was developed at the first AWV providing PPPS, and,

(2) The list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are under way for the individual, as that list was developed at the first AWV providing PPPS *or the previous subsequent AWV providing PPPS.*

g. Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined for the first AWV providing PPPS.

h. Any other element determined appropriate by the Secretary through the NCD process.

See Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 140, for detailed claims processing and billing instructions.

Medicare Benefit Policy Manual
Chapter 16 - General Exclusions From Coverage

90 - Routine Services and Appliances

(Rev. 170, Issued: 05-10-13, Effective: 01-01-12, Medicare Coverage of the Annual Wellness Visit (AWV); 01-01-13- Medicare Coverage of Hepatitis B Vaccine, Implementation: 06-10-13)

Routine physical checkups; eyeglasses, contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses; eye refractions by whatever practitioner and for whatever purpose performed; hearing aids and examinations for hearing aids; and immunizations are not covered.

The routine physical checkup exclusion applies to (a) examinations performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury; and (b) examinations required by third parties such as insurance companies, business establishments, or Government agencies.

The routine physical checkup exclusion does not apply to the following services (as noted in section 42 CFR 411.15(a)(1)):

- *Screening mammography,*
- *Colorectal cancer screening tests,*
- *Screening pelvic exams,*
- *Prostate cancer screening tests,*
- *Glaucoma screening exams,*
- *Ultrasound screening for abdominal aortic aneurysms (AAA),*
- *cardiovascular disease screening tests,*
- *diabetes screening tests,*
- *screening electrocardiogram,*
- *Initial preventive physical examinations,*
- *Annual wellness visits providing personalized prevention plan services, and*
- *Additional preventive services that meet the criteria specified in 42 CFR 410.64.*

If the claim is for a diagnostic test or examination performed solely for the purpose of establishing a claim under title IV of Public Law 91-173, “Black Lung Benefits,” the service is not covered under Medicare and the claimant should be advised to contact their Social Security office regarding the filing of a claim for reimbursement under the “Black Lung” program.

The exclusions apply to eyeglasses or contact lenses, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive errors. The exclusions do not apply to physicians’ services (and services incident to a physicians’ service) performed in conjunction with an eye disease, as for example, glaucoma or cataracts, or to post-surgical prosthetic lenses which are customarily used

during convalescence from eye surgery in which the lens of the eye was removed, or to permanent prosthetic lenses required by an individual lacking the organic lens of the eye, whether by surgical removal or congenital disease. Such prosthetic lens is a replacement for an internal body organ - the lens of the eye. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120).

Expenses for all refractive procedures, whether performed by an ophthalmologist (or any other physician) or an optometrist and without regard to the reason for performance of the refraction, are excluded from coverage.

A. Immunizations

Vaccinations or inoculations are excluded as immunizations unless they are either

- Directly related to the treatment of an injury or direct exposure to a disease or condition, such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. (In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered.); or

- Specifically covered by statute, as described in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.*4.4.2*.

B. Antigens

Prior to the Omnibus Reconciliation Act of 1980, a physician who prepared an antigen for a patient could not be reimbursed for that service unless the physician also administered the antigen to the patient. Effective January 1, 1981, payment may be made for a reasonable supply of antigens that have been prepared for a particular patient even though they have not been administered to the patient by the same physician who prepared them if:

- The antigens are prepared by a physician who is a doctor of medicine or osteopathy, and

- The physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

A reasonable supply of antigens is considered to be not more than a 12-week supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.4.4.*1*)