Medicare
Intermediary Manual
Part 3 - Claims Process

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
3628 (Cont.) - 3628.2 (Cont.)	6-165.2 - 6-166.6 (8 pp.)	6-165.2 - 6-166.5 (7 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2001*
IMPLEMENTATION DATE: July 1, 2001

Section 3628.1, Screening Pap Smears and Screening Pelvic Examinations, is being updated to reflect the Consolidated Appropriations Act of 2001, Public Law 106-554, which modifies current law to provide Medicare coverage for biennial screening Pap smears and pelvic exams.

This instruction also updates the applicable bill types and payment methods for these benefits.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

EXHIBIT 3

Laboratory Services Furnished To A Medicare Beneficiary In An SNF

Inpatient in Part A stay (who also has Part B coverage)

o Furnished by SNF "in-house" lab	SNF bills intermediary. Payment is made on Part A reasonable cost basis.
o Furnished under arrangements by hospital with transfer agreement with SNF	Hospital bills SNF. SNF bills intermediary. Payment is on Part A reasonable cost basis.
o Furnished by any other lab, including another SNF or hospital with out a transfer agreement with the SNF	No Part A coverage is available. Only the lab that furnished the service can billing under Part B and payment is made using the lab fee schedule. A provider (i.e., hospital or another SNF) bills its intermediary. Other entities bill their carriers.

Inpatient **not in** Part A stay who has Part B coverage

o Furnished by SNF "in-house" lab	SNF bills intermediary. Payment is Part B reasonable cost.
o Furnished by any other lab, including another SNF or any hospital	Only the lab that furnished the service can bill under Part B and payment is made using the lab fee schedule. A provider (i.e., hospital or another SNF) bills its intermediary. other entities bill their carriers.

SNF outpatient

o Furnished by "in-house" lab or any other lab	Only the lab that furnished the service can bill under Part B and payment is made using the lab fee schedule. A provider (i.e., hospital or SNF) bills its intermediary. Other entities bill their carriers.

3628.1 Screening Pap Smears and Screening Pelvic Examinations.--

A. Screening Pap Smear.--Effective, January 1, 1998, §4102 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) amended §1861(nn) of the Social Security Act (the Act) (42 USC 1395X(nn) to include coverage every 3 years for a screening Pap smear or more frequent coverage for women (1) at high risk for cervical or vaginal cancer, or (2) of childbearing age who have had a Pap smear during any of the preceding 3 years indicating the presence of cervical or vaginal cancer or other abnormality. Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861 (nn) to provide Medicare coverage for biennial screening Pap smears. Specifications for frequency limitations are defined below.

1. Coverage.--For claims with dates of service from January 1, 1998, through June 30, 2001, screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy (as defined in §1861(r)(l) of the Act), or other authorized practitioner (e.g., a certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist, who is authorized under State law to perform the examination) under one of the following conditions:

o The beneficiary has not had a screening Pap smear test during the preceding 3 years (i.e., 35 months have passed following the month that the woman had the last covered Pap smear). Use ICD-9-CM code V76.2, special screening for malignant neoplasm, cervix); or

o There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding 3 years; or that she is at high risk of developing cervical or vaginal cancer (use ICD-9-CM code V15.89, other specified personal history presenting hazards to health). The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors:

-- Early onset of sexual activity (under 16 years of age);

-- Multiple sexual partners (five or more in a lifetime);

-- History of a sexually transmitted disease (including HIV infection); and

-- Fewer than three negative or any Pap smears within the previous 7 years.

Vaginal Cancer High Risk Factors:

-- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

The term "woman of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening Pap smear for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening Pap smear covered by Medicare was performed.

For claims with dates of service on or after July 1, 2001, when the beneficiary does not meet the criteria noted above for an annual screening Pap smear, pay for a screening Pap smear only after at least 23 months have passed following the month during which the beneficiary received her last covered screening Pap smear. All other coverage and payment requirements remain the same.

2. HCPCS Coding.--The following HCPCS codes are used for screening Pap smears:

o P3000--Screening papanicolaou smear, cervical or vaginal, up to three smears, by a technician under the physician supervision.

o G0123--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, evaluation by cytotechnologist under physician supervision.

o G0143--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and reevaluation by cytotechnologist under physician supervision.

o G0144--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and computer-assisted reevaluation by cytotechnologist under physician supervision.

o G0145--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual evaluation and computer-assisted reevaluation using cell selection and review under physician supervision

o G0147--Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision.

o G0148--Screening cytopathology smears, cervical or vaginal, performed by automated system with manual reevaluation.

3. Payment.--Screening Pap smears are paid under the clinical diagnostic laboratory fee schedule with the exception of RHCs/FQHCs which are paid as follows:

o On an all inclusive rate for the professional component; or

o Under the clinical diagnostic laboratory fee schedule for the technical component.

Deductible and coinsurance do not apply.

4. Billing Requirements.--The applicable bill types for screening Pap smears are 13X, 14X, 22X, 23X, 75X and 85X. The applicable revenue code is 311. (See below for rural health clinics (RHCs) and federally qualified health centers (FQHCs.)

The professional component of a screening Pap smear furnished within an RHC/FQHC by a physician or non-physician is considered an RHC/FQHC service. RHCs and FQHCs bill you under bill type 71X or 73X for the professional component along with revenue code 52X

The technical component of a screening Pap smear is outside the scope of the RHC/FQHC benefit. If the technical component of this service is furnished within an independent RHC or free-standing FQHC, the provider of that technical service bills the carrier on Form HCFA-1500.

If the technical component of a screening Pap smear is furnished within a provider-based RHC/FQHC, the provider of that service bills you under bill type 13X, 14X, 22X, 23X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services).The appropriate revenue code is 311.

B. Screening Pelvic Examinations.--Section 4102 of the BBA of 1997 (P.L. 105-33) amended §1861(nn) of the Act (42 USC 1395X(nn)) to include coverage of a screening pelvic examination for all female beneficiaries, effective January 1, 1998. Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening pelvic examinations. Specifications for frequency limitations are defined below. A screening pelvic examination should include at least 7 of the following 11 elements:

- Inspection and palpation of breasts for masses or lumps, tenderness, symmetry, or nipple discharge;

- Digital rectal examination including sphincter tone, presence of hemorrhoids, and rectal masses;

Pelvic examination (with or without specimen collection for smears and culture) including:

- External genitalia (for example, general appearance, hair distribution, or lesions);

- Urethral (for example, masses, tenderness, or scarring);

- Bladder (for example, fullness, masses, or tenderness);

- Vagina (for example, general appearance, estrogen effect, discharge, lesions, pelvic support, cystocele, or rectocele);

- Cervix (for example, general appearance, lesions or discharge);

- Uterus (for example, size, contour, position, mobility, tenderness, consistency, descent, or support);

- Adnexa/parametria (for example, masses, tenderness, organomegaly, or nodularity); and

- Anus and perineum.

1. Coverage.--For claims with dates of service from January 1, 1998, through June 30, 2001, Medicare Part B pays for a screening pelvic examination if it is performed by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or by a certified nurse midwife (as defined in §1861 (gg) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861 (aa) of the Act) who is authorized under State law to perform the examination. This examination does not have to be ordered by a physician or other authorized practitioner.

Payment may be made for a screening pelvic examination performed on an asymptomatic woman only if the individual has not had a screening pelvic examination paid for by Medicare during the preceding 35 months following the month in which the last Medicare covered screening pelvic examination was performed. (Use ICD-9-CM code V76.2, special screening for malignant neoplasm, cervix, or code V76.49 for a patient who does not have a uterus or cervix.) Exceptions are as follows:

- Payment may be made for a screening pelvic examination performed more frequently than once every 35 months if the test is performed by a physician or other practitioner and there is evidence that the woman is at high risk (on the basis of her medical history or other findings) of developing cervical cancer, or vaginal cancer. (Use ICD-9-CM code V15.89, other specified personal history presenting hazards to health.) The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors:

-- Early onset of sexual activity (under 16 years of age);

-- Multiple sexual partners (five or more in a lifetime);

-- History of a sexually transmitted disease (including HIV infection); and

-- Fewer than three negative or any Pap smears within the previous 7 years.

Vaginal Cancer High Risk Factors:

-- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.

o Payment may also be made for a screening pelvic examination performed more frequently than once every 36 months if the examination is performed by a physician or other practitioner, for a woman of childbearing age, who has had such an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term "women of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening pelvic examination for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

For claims with dates of service on or after July 1, 2001, if the beneficiary does not qualify for an annual screening pelvic exam as noted above, pay for the screening pelvic exam only after at least 23 months have passed following the month during which the beneficiary received her last covered screening pelvic exam. All other coverage and payment requirements remain the same.

2. HCPCS Coding.--The following HCPCS code is used for screening pelvic examinations:

o G0101--Cervical or vaginal cancer screening pelvic and clinical breast examination.

3. Payment.--Screening pelvic examinations are paid as follows when provided in a:

o Hospital outpatient department--payment is under the outpatient prospective payment system (OPPS);

o A skilled nursing facility (SNF) or comprehensive outpatient rehabilitation facility (CORF)--payment is under the Medicare Physician Fee Schedule;

o A critical access hospital (CAH)--payment is made on a reasonable cost basis; or

o RHCs/FQHCs--payment is made on an all inclusive rate for the professional component; or based on the providers payment method for the technical component. (See subsection 4 below for proper billing by RHC/FQHCs for the professional and technical components of a screening pelvic examination.)

The Part B deductible for screening pelvic examinations is waived effective January 1, 1998. Coinsurance applies.

4. Billing Requirements.--The applicable bill types for a screening pelvic examination (including breast examination) are 13X, 14X, 22X, 23X, 75X and 85X. The applicable revenue code is 770. (See below for RHCs and FQHCs.)

The professional component of a screening pelvic examination furnished within an RHC/FQHC by a physician or non-physician is considered an RHC/FQHC service. RHCs and FQHCs bill you under bill type 71X or 73X for the professional component along with revenue code 52X.

The technical component of a screening pelvic examination is outside the scope of the RHC/FQHC benefit. If the technical component of this service is furnished within an independent RHC or free-standing FQHC, the provider of that technical service bills the carrier on Form HCFA-1500.

If the technical component of a screening pelvic examination is furnished within a provider-based RHC/FQHC, the provider of that service bills you under bill type 13X, 14X, 22X, 23X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services). The appropriate revenue code is 770.

When a claim is received for a screening pelvic examination (including a clinical breast examination), performed on or after January 1, 1998, report special override Code 1 in field 65j "Special Action" of the CWF record to avoid application of the Part B deductible.

C. Screening Pap Smears and Screening Pelvic Examinations.--

1. CWF Edits.--CWF will edit for screening Pap smear and/or screening pelvic examination performed more frequently than allowed according to the presence of high risk factors.

2. Medicare Summary Notices (MSN) and Explanation of Your Medicare Benefits (EOMB) Messages.--If there are no high risk factors, and the screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed, use the following MSN or EOMB message:

"Medicare pays for screening Pap smear and/or screening pelvic examination only once every (2/3) years unless high risk factors are present." (MSN Message 18-17, EOMB Message 18.26.)

3. Remittance Advice Notices.--If high risk factors are not present, and the screening Pap smear and/or screening pelvic examination is being denied because the procedure/examination is performed more frequently than allowed, use existing American National Standard Institute (ANSI) X12-835 claim adjustment reason code 119, "Benefit maximum for this time period has been reached," at the line level, along with line level remark code M83, "Service is not covered unless the beneficiary is classified as at high risk."

3628.2 Clinical Laboratory Improvement Amendments (CLIA).--

A. Background.--CLIA of 1988 changes clinical laboratories' certification. Effective September 1, 1992, pay clinical laboratory services only if the entity furnishing laboratory services has been issued a CLIA number.

However, laboratories may be paid for a limited number of laboratory services if they have a CLIA certificate of waiver or a certificate for physician-performed microscopy procedures. These laboratories are not subject to routine on-site surveys.

B. General.--For hospital, SNF, and hospice general inpatient care claims, providers are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that laboratory services are provided by approved laboratories.

C. Other.--For HHA and renal dialysis facility claims, do not attempt to validate CLIA certification against payment. Freestanding HHAs and ESRD facilities cannot bill for laboratory tests. The survey process is used to validate that laboratory services in HHAs and ESRD facilities are being provided in accordance with the CLIA certificate. You do not need to take action.

D. CLIA Numbers.--Use the following CLIA positions:

o Positions 1 and 2 are the State code (based on the laboratory's physical location at time of registration);

o Position 3 is an alpha letter "D"; and

o Positions 4-10 are a unique number assigned by the CLIA billing system. (No other lab in the country will have this number.)

E. Certificate for Physician-Performed Microscopy Procedures.--Effective January 19, 1993, a laboratory that holds a certificate for physician-performed microscopy procedures may perform only those tests specified as physician-performed microscopy procedures and waived tests, as described in §3628.2 subsection F, and no others. The following codes may be used:

HCPCS Code	Test
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens;
Q0112	All potassium hydroxide (KOH) preparations;
Q0113	Pinworm examinations;
Q0114	Fern test;
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous; and
81015	Urine sediment examinations.

F. Certificate of Waiver.--Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver or certificate of registration to legally perform clinical laboratory testing anywhere in the United States.

A grace period starting May 1, 1993, and ending July 31, 1993, has been granted to allow providers time to adapt to the new coding system. Physicians, suppliers, and providers may submit claims for services furnished during this grace period with 1992 or 1993 lab codes.

Claims for services provided prior to the grace period (prior to May 1, 1993) must reflect 1992 codes, even if received after the end of the grace period (after July 1, 1993). Deny claims with dates of services prior to May 1, 1993, which reflect 1993 codes.

Payment for covered laboratory services furnished on or after September 1, 1992, by laboratories with a certificate of waiver is limited to the following eight procedures:

HCPCS Code	
1992	1993

Q0095	81025	Urine pregnancy test; visual color comparison tests;
Q0096	84830	Ovulation test; visual color comparison test for human luteinizing hormone;
Q0097	83026	Hemoglobin; by copper sulfate method, non-automated;
Q0098	82962	Glucose, blood; by glucose monitoring devices cleared by the FDA specifically for home use;
82270	82270	Blood, occult; feces;
Q0100	81002	Urinalysis by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of constituents; non-automated, without microscopy;
Q0101	85013	Microhematocrit; spun; and
Q0102	85651	Sedimentation rate, erythrocyte; non-automated.

Effective January 19, 1993, a ninth test was added to the waived test list:

Q0116 Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

G. Under Arrangements.--When a hospital obtains laboratory tests for outpatients or nonpatients under arrangements with independent laboratories or other hospital laboratories, the hospital must be sure that the laboratory performing the services has a CLIA number.

H. Certificate of Registration.--Initially, providers are issued CLIA numbers when they apply to the CLIA program. Pay for all covered laboratory services furnished on or after September 1, 1992, if the laboratory has a certificate of registration.