Medicare
Intermediary Manual
Part 3 - Claims Process

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 2586

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
3628 (Cont.) – 3628.1 (Cont.)	6-165.2 – 6-166.4a (7 pp.)	6-165.2 – 6-166.4 (6 pp.)

MANUALIZATION--*EFFECTIVE DATE:* Not applicable

Section 3628, Clinical Diagnostic Laboratory Services Other Than To Inpatients, revises Exhibit 3 to reflect the correct payment methodology for SNF patients.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2003*
--IMPLEMENTATION DATE: July 1, 2003

Section 3628.1, Screening Pap Smears and Screening Pelvic Examinations, is revised to include code Q0091 for the billing of screening Pap smears which was inadvertently left out of prior instructions. It also lists the appropriate payment and revenue code for this code. Definitions for the other allowable HCPCS codes are being updated for definition clarification. Also, the 75X bill type has been removed from this benefit.

You must notify providers of this new billing information in your next regularly scheduled bulletin and post on your Web site within two weeks of receiving this instruction.

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.

These instructions should be implemented within your current operating budget.

EXHIBIT 3

Laboratory Services Furnished To A Medicare Beneficiary In An SNF

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

o Furnished by SNF	SNF bills intermediary. Payment is made as part of the SNF PPS payment.
o Furnished under arrangements by hospital with transfer agreement with SNF	Hospital bills SNF. SNF bills intermediary. Payment is made as part of the SNF PPS payment.
o Furnished by any other lab, including another SNF or hospital with out a transfer agreement with the SNF	SNF bills intermediary. Payment is made as part. of the SNF PPS payment

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

o Furnished by SNF "in-house" lab	SNF bills intermediary. Payment is made on the Clinical Diagnostic Laboratory Fee Schedule.
o Furnished by any other lab, including another SNF or any hospital	SNF bills intermediary. Payment is made on the Clinical Diagnostic Laboratory Fee Schedule.

SNF outpatient

o Furnished by "in-house" lab or any other lab	SNF bills intermediary. Payment is made on the Clinical Diagnostic Laboratory Fee Schedule.

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 Q0091—Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory. (See item 4 below for payment of this code.)

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

o G0144--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system, under physician supervision.

o G0145--Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with screening by automated system and manual rescreening 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 for Other than Code Q0091.--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. Payment for Code Q0091.--Payment for code Q0091 is as follows:

o Hospital outpatient departments payment is made under OPPS;

o SNFs payment is made on the physician fee schedule;

o CAHs payment is made on a reasonable cost basis unless the CAH elects Method II. Payment is made under Method II as indicated in §3610.22.

For RHCs/FQHCs payment is as follows:

o For the professional component (freestanding and provider based) payment is made based on the all inclusive rate;

o For the technical component, independent RHCs/FQHCs bill the carrier on the Form CMS-1500 and are paid based on the Medicare Physician Fee Schedule (MPFS); and

o For the technical component, provider based RHCs/FQHCs are paid based on the provider type as indicated in the bullet points above.

Medicare deductible is not applicable. However, coinsurance applies.

5. Bundled to the SNF for Beneficiaries in a covered Part A Stay. Bill for screening pap smears, like all screening and preventive services, on type of bill 22X, if the beneficiary is in a covered Part A stay. If the beneficiary is a Part B resident, there is no bundling requirement.

6. Billing Requirements.--The applicable bill types for screening Pap smears are 13X, 14X, 22X, 23X, and 85X. The applicable revenue code for P3000, G0123, G0143, G0144, G0145, G0147, and G0148 is 0311. The applicable revenue code for Q0091 is 0923. For proper reporting of revenue codes for CAHs, see §3610.22B2b. (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 052X.

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 CMS-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 0311.

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:

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

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

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

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

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

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

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

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

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

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

o 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:

o 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
-- 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 12X,13X, 14X, 22X, 23X, and 85X. The applicable revenue code is 0770. (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 052X.

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 CMS-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 0 770.

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.