106TH CONGRESS
2D SESSION

H. R. 5661

To amend titles XVIII, XIX, and XXI of the Social Security Act to provide benefits improvements and beneficiary protections in the Medicare and Medicaid Programs and the State child health insurance program (SCHIP), as revised by the Balanced Budget Act of 1997 and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 14, 2000

Mr. THOMAS (for himself, Mr. BLILEY, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend titles XVIII, XIX, and XXI of the Social Security Act to provide benefits improvements and beneficiary protections in the Medicare and Medicaid Programs and the State child health insurance program (SCHIP), as revised by the Balanced Budget Act of 1997 and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

Alan S. Goldberg's Law, Technology & Change Home Page SM

www.healthlawyer.com
www.brownfieldslawyer.com
www.ecommercelawyer.com
www.hipaalawyer.com
www.pkilawyer.com
www.housinglawyer.com
www.healthfraud.com
www.telemedicinelawyer.com
www.ucitalawyer.com
www.esignlawyer.com

Contact Alan S. Goldberg*, Webmaster

Via Internet Email

(888) 777-0566

400 Atlantic Av., Boston, MA 02110
Voice (617) 482-1776 -- Fax (617) 574-4112
1717 Pennsylvania Av., NW, Washington, DC 20006
Voice (202) 721-0011 -- Fax (202) 721-1111

***Not admitted in DC**

Please read our *Year 2000 Readiness Disclosure* for this Web site

By entering this Web site, you agree to our *Disclaimer*

Please read our *Privacy Policy*

Expansion of Medicare Part B Reimbursement for Telehealth under THE MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000
Statute, Program Memorandum for Intermediaries/Carriers, Comments & Final Rule

Anti-Terrorism Legislation

HR 3162

1 **SEC. 223. REVISION OF MEDICARE REIMBURSEMENT FOR**
2 **TELEHEALTH SERVICES.**

3 (a) TIME LIMIT FOR BBA PROVISION.—Section
4 4206(a) of BBA (42 U.S.C. 1395l note) is amended by
5 striking ‘‘Not later than January 1, 1999’’ and inserting
6 ‘‘For services furnished on and after January 1, 1999, and
7 before October 1, 2001’’.

8 (b) EXPANSION OF MEDICARE PAYMENT FOR TELE-
9 HEALTH SERVICES.—Section 1834 (42 U.S.C. 1395m) is
10 amended by adding at the end the following new sub-
11 section:

12 ‘‘(m) PAYMENT FOR TELEHEALTH SERVICES.—

13 ‘‘(1) IN GENERAL.—The Secretary shall pay for
14 telehealth services that are furnished via a tele-
15 communications system by a physician (as defined in
16 section 1861(r)) or a practitioner (described in sec-
17 tion 1842(b)(18)(C)) to an eligible telehealth indi-
18 vidual enrolled under this part notwithstanding that
19 the individual physician or practitioner providing the
20 telehealth service is not at the same location as the
21 beneficiary. For purposes of the preceding sentence,
22 in the case of any Federal telemedicine demonstra-
23 tion program conducted in Alaska or Hawaii, the
24 term ‘telecommunications system’ includes store-
25 and-forward technologies that provide for the asyn-

1 chronous transmission of health care information in
2 single or multimedia formats.
3 ‘‘(2) PAYMENT AMOUNT.—
4 ‘‘(A) DISTANT SITE.—The Secretary shall
5 pay to a physician or practitioner located at a
6 distant site that furnishes a telehealth service
7 to an eligible telehealth individual an amount
8 equal to the amount that such physician or
9 practitioner would have been paid under this
10 title had such service been furnished without
11 the use of a telecommunications system.
12 ‘‘(B) FACILITY FEE FOR ORIGINATING
13 SITE.—With respect to a telehealth service, sub-
14 ject to section 1833(a)(1)(U), there shall be
15 paid to the originating site a facility fee equal
16 to—
17 ‘‘(i) for the period beginning on Octo-
18 ber 1, 2001, and ending on December 31,
19 2001, and for 2002, $20; and
20 ‘‘(ii) for a subsequent year, the facil-
21 ity fee specified in clause (i) or this clause
22 for the preceding year increased by the
23 percentage increase in the MEI (as defined
24 in section 1842(i)(3)) for such subsequent
25 year.

1 "(C) TELEPRESENTER NOT REQUIRED.—
2 Nothing in this subsection shall be construed as
3 requiring an eligible telehealth individual to be
4 presented by a physician or practitioner at the
5 originating site for the furnishing of a service
6 via a telecommunications system, unless it is
7 medically necessary (as determined by the phy-
8 sician or practitioner at the distant site).
9 "(3) LIMITATION ON BENEFICIARY CHARGES.—
10 "(A) PHYSICIAN AND PRACTITIONER.—
11 The provisions of section 1848(g) and subpara-
12 graphs (A) and (B) of section 1842(b)(18) shall
13 apply to a physician or practitioner receiving
14 payment under this subsection in the same
15 manner as they apply to physicians or practi-
16 tioners under such sections.
17 "(B) ORIGINATING SITE.—The provisions
18 of section 1842(b)(18) shall apply to originating
19 sites receiving a facility fee in the same manner
20 as they apply to practitioners under such sec-
21 tion.
22 "(4) DEFINITIONS.—For purposes of this sub-
23 section:
24 "(A) DISTANT SITE.—The term 'distant
25 site' means the site at which the physician or

1 practitioner is located at the time the service is
2 provided via a telecommunications system.
3 "(B) ELIGIBLE TELEHEALTH INDI-
4 VIDUAL.—The term 'eligible telehealth indi-
5 vidual' means an individual enrolled under this
6 part who receives a telehealth service furnished
7 at an originating site.
8 "(C) ORIGINATING SITE.—
9 "(i) IN GENERAL.—The term 'origi-
10 nating site' means only those sites de-
11 scribed in clause (ii) at which the eligible
12 telehealth individual is located at the time
13 the service is furnished via a telecommuni-
14 cations system and only if such site is
15 located—
16 "(I) in an area that is designated
17 as a rural health professional shortage
18 area under section 332(a)(1)(A) of
19 the Public Health Service Act (42
20 U.S.C. 254e(a)(1)(A));
21 "(II) in a county that is not in-
22 cluded in a Metropolitan Statistical
23 Area; or
24 "(III) from an entity that partici-
25 pates in a Federal telemedicine dem-

1 onstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

"(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

"(I) The office of a physician or practitioner.

"(II) A critical access hospital (as defined in section 1861(mm)(1)).

"(III) A rural health clinic (as defined in section 1861(aa)(s)).

"(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

"(V) A hospital (as defined in section 1861(e)).

"(D) PHYSICIAN.—The term 'physician' has the meaning given that term in section 1861(r).

"(E) PRACTITIONER.—The term 'practitioner' has the meaning given that term in section 1842(b)(18)(C).

"(F) TELEHEALTH SERVICE.—

1 "(i) IN GENERAL.—The term 'tele-
2 health service' means professional con-
3 sultations, office visits, and office psychi-
4 atry services (identified as of July 1, 2000,
5 by HCPCS codes 99241–99275, 99201–
6 99215, 90804–90809, and 90862 (and as
7 subsequently modified by the Secretary)),
8 and any additional service specified by the
9 Secretary.
10 "(ii) YEARLY UPDATE.—The Sec-
11 retary shall establish a process that pro-
12 vides, on an annual basis, for the addition
13 or deletion of services (and HCPCS codes),
14 as appropriate, to those specified in clause
15 (i) for authorized payment under para-
16 graph (1).".
17 (c) CONFORMING AMENDMENT.—Section 1833(a)(1)
18 (42 U.S.C. 1395l(1)), as amended by section 105(c), is
19 further amended—
20 (1) by striking "and (T)" and inserting "(T)";
21 and
22 (2) by inserting before the semicolon at the end
23 the following: ", and (U) with respect to facility fees
24 described in section 1834(m)(2)(B), the amounts

1 paid shall be 80 percent of the lesser of the actual
2 charge or the amounts specified in such section''.
3 (d) STUDY AND REPORT ON ADDITIONAL COV-
4 ERAGE.—
5 (1) STUDY.—The Secretary of Health and
6 Human Services shall conduct a study to identify—
7 (A) settings and sites for the provision of
8 telehealth services that are in addition to those
9 permitted under section 1834(m) of the Social
10 Security Act, as added by subsection (b);
11 (B) practitioners that may be reimbursed
12 under such section for furnishing telehealth
13 services that are in addition to the practitioners
14 that may be reimbursed for such services under
15 such section; and
16 (C) geographic areas in which telehealth
17 services may be reimbursed that are in addition
18 to the geographic areas where such services
19 may be reimbursed under such section.
20 (2) REPORT.—Not later than 2 years after the
21 date of the enactment of this Act, the Secretary
22 shall submit to Congress a report on the study con-
23 ducted under paragraph (1) together with such rec-
24 ommendations for legislation that the Secretary de-
25 termines are appropriate.

(e) EFFECTIVE DATE.—The amendments made by subsections (b) and (c) shall be effective for services furnished on or after October 1, 2001.

SEC. 224. EXPANDING ACCESS TO RURAL HEALTH CLINICS.

(a) IN GENERAL.—The matter in section 1833(f) (42 U.S.C. 1395l(f)) preceding paragraph (1) is amended by striking "rural hospitals" and inserting "hospitals".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to services furnished on or after July 1, 2001.

SEC. 225. MEDPAC STUDY ON LOW-VOLUME, ISOLATED RURAL HEALTH CARE PROVIDERS.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the effect of low patient and procedure volume on the financial status of low-volume, isolated rural health care providers participating in the medicare program under title XVIII of the Social Security Act.

(b) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under subsection (a) indicating—

(1) whether low-volume, isolated rural health care providers are having, or may have, significantly decreased medicare margins or other financial dif-

Program Memorandum Intermediaries/Carriers

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

Transmittal AB-01-69 | **Date: MAY 1, 2001**

CHANGE REQUEST 1650

SUBJECT: Revision of Medicare Reimbursement for Telehealth Services

This Program Memorandum (PM) contains policy and billing instructions implementing §223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services. BIPA amended §1834 of the Social Security Act (the Act) to provide for an expansion of Medicare payment for telehealth services.

Section 223 of BIPA limits the existing telehealth provision to services furnished before October 1, 2001, and mandates that the expanded benefit be effective for services furnished on or after October 1, 2001. Therefore, this benefit expansion is being implemented via a PM. Conforming regulation text changes will follow this instruction.

Summary

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy and pharmacologic management delivered via a telecommunications system. Eligible geographic areas will be expanded beyond rural health professional shortage areas to include counties not in a metropolitan statistical area (MSA). Additionally, Federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location. An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous 'store and forward' technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specifies that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) will be equal to what would have been paid without the use of telemedicine. Distant site practitioners include only a physician as described in §1861(r) and a medical practitioner as described in §1842(b)(18) (C) of the Act. BIPA also expands payment under Medicare to include a $20 originating site facility fee (location of beneficiary).

Previously, the Balanced Budget Act of 1997 (BBA) limited the scope of Medicare telehealth coverage to consultation services and the implementing regulation prohibited the use of an asynchronous, 'store and forward' telecommunications system. BBA 1997 also required the professional fee to be shared between the referring and consulting practitioners, and prohibited Medicare payment for facility fees and line charges associated with the telemedicine encounter.

BIPA requires that Medicare Part B (Supplementary Medical Insurance) pay for this expansion of telehealth services beginning with services furnished on October 1, 2001.

Time limit for current teleconsultation provision. The current teleconsultation provision as authorized by §4206 (a) and (b) of the BBA of 1997 and implemented in 42 CFR §§410.78 and 414.65 applies only to teleconsultations provided on or after January 1, 1999, and before October 1, 2001.

Expansion of Medicare Payment for Telehealth Services

Eligibility Criteria

Beneficiaries eligible for telehealth services. Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area (HPSA) as defined by §332(a)(1) (A) of the Public Health Services Act or in a county outside of a MSA as defined by §1886(d)(2)(D) of the Act.

Exception to rural HPSA and non MSA geographic requirements. Entities participating in a Federal telemedicine demonstration project that were approved by or were receiving funding from the Secretary of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location. Such entities are not required to be in a rural HPSA or non-MSA.

Originating site defined. An originating site is the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Originating sites authorized by law are listed below.

- The office of a physician or practitioner.
- A hospital.
- A critical access hospital.
- A rural health clinic.
- A federally qualified health center.

Coverage of Telehealth

Scope of coverage. The use of a telecommunications system may substitute for a face-to-face, "hands on" encounter for consultation, office visits, individual psychotherapy and pharmacologic management. These services and corresponding current procedure terminology (CPT) codes are listed below.

- Consultations (CPT codes 99241 - 99275).
- Office or other outpatient visits (CPT codes 99201 - 99215).
- Individual psychotherapy (CPT codes 90804 - 90809).
- Pharmacologic management (CPT code 90862).

Conditions of Payment

Technology. For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

Exception to the interactive telecommunications requirement. In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous 'store and forward technology', in single or multimedia formats, is used as a substitute for an interactive telecommunications system. The originating site and distant site practitioner must be included within the definition of the demonstration program.

Store and forward defined. For purposes of this instruction, store and forward means the asynchronous transmission of medical information to be reviewed at a later time by physician or practitioner at the distant site. A patient's medical information may include, but not limited to, video clips, still images, x-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.

NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis and or treatment plan. Dermatological photographs, e.g., a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

Telepresenters. A medical professional is not required to present the beneficiary to physician or practitioner at the distant site unless medically necessary. The decision of medical necessity will be made by the physician or practitioner located at the distant site.

Payment Methodology for Physician/Practitioner at the Distant Site

Distant site defined. The term "distant site" means the site where the physician or practitioner, providing the professional service, is located at the time the service is provided via a telecommunications system.

Payment amount (professional fee). The payment amount for the professional service provided via a telecommunications system by the physician or practitioner at the distant site is equal to the current fee schedule amount for the service provided. Payment for an office visit, consultation, individual psychotherapy or pharmacologic management via a telecommunications system should be made at the same amount as when these services are furnished without the use of a telecommunications system. For Medicare payment to occur, the service must be within a practitioner's scope of practice under State law. The beneficiary is responsible for any unmet deductible amount and applicable coinsurance.

Medicare practitioners who may receive payment at the distant site (i.e., at a site other than where beneficiary is). As a condition of Medicare Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under State law. When the physician or practitioner at the distant site is licensed under State law to provide a covered telehealth service (i.e., professional consultation, office and other outpatient visits, individual psychotherapy, and pharmacologic management) then he or she may bill for and receive payment for this service when delivered via a telecommunications system.

Medicare practitioners who may bill for covered telehealth services are listed below (subject to State law).

- Physician.
- Nurse practitioner.
- Physician assistant.
- Nurse midwife.
- Clinical nurse specialist.
- Clinical psychologist.*
- Clinical social worker.*

*Clinical psychologists and clinical social workers cannot bill for psychotherapy services that include medical evaluation and management services under Medicare. These practitioners may not bill or receive payment for the following CPT codes: 90805, 90807, and 90809.

Originating Site Facility Fee Payment Methodology

Originating site defined. The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous, store and forward telecommunications technologies, an originating site is only a Federal telemedicine demonstration program conducted in Alaska or Hawaii.

Facility fee for originating site. For consultation, office or other outpatient visit, psychotherapy and pharmacologic management services delivered via a telecommunications system furnished from October 1, 2001, through December 31, 2002, the originating site fee is the lesser of $20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated annually by the Medicare Economic Index (MEI).

Payment amount. For telehealth services furnished from October 1, 2001, through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance. The originating site facility fee payment methodology for each type of facility is clarified below.

- Hospital outpatient department. When the originating site is a hospital outpatient department, payment for the originating site facility fee must be made as described above and not under the outpatient prospective payment system. Payment is not based on current fee schedules or other payment methodologies.

- Hospital inpatient. For hospital inpatients, payment for the originating site facility fee must be made outside the Diagnostic related group (DRG) payment, since this is a Part B benefit, similar to other services paid separately from the DRG payment, (e.g., hemophilia blood clotting factor).

- Critical access hospitals. When the originating site is a critical access hospital, make payment as described above, separately from the cost-based reimbursement methodology.

- Federally qualified health centers (FQHCs) and rural health clinics (RHCs). The originating site facility fee for telehealth services is not an FQHC or RHC service. When an FQHC or RHC serves as the originating site, the originating site facility fee must be paid separately from the center or clinic all-inclusive rate.

- Physicians' and practitioners' offices. When the originating site is a physician's or practitioner's office, the payment amount, in accordance with the law, is the lesser of the actual charge or $20 regardless of geographic location. Do not apply the geographic practice cost index (GPCI) to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician fee schedule.

Submission of Telehealth Claims

Carrier and Intermediary Instructions

Carriers and intermediaries must publish information concerning the changes outlined in this PM in their next regularly scheduled bulletin as well as on their websites.

Professional Service - *Carriers*

Distant site practitioners. Claims for professional consultations, office visits, individual psychotherapy, and pharmacologic management provided via a telecommunications systems for dates of service October 1, 2001, and later must be submitted to the carriers that processes claims for the practitioners service area. Submit such claims with the appropriate CPT code for the professional service provided and the telehealth modifier "GT" – "via interactive audio and video telecommunications system."

By using the "GT" modifier to bill for the telehealth service, the distant site practitioner verifies that the beneficiary was located at an eligible originating site at the time of the telehealth service.

Exception for store and forward (non-interactive) telehealth. In the case of a Federal telemedicine demonstration program conducted in Alaska or Hawaii, store and forward technologies may be used as a substitute for an interactive telecommunications system. When store and forward technologies are used, submit the appropriate CPT code and telehealth modifier "GQ", "via asynchronous telecommunications system."

(See "Store and forward defined" and "Medical practitioners who may receive payment at the distant site" sections).

By using the "GQ" modifier, the distant site practitioner verifies that the asynchronous medical file was collected and transmitted to the physician or practitioner at the distant site from a Federal telemedicine demonstration project conducted in Alaska or Hawaii. (See "Eligibility Criteria" and "Conditions of Payment" sections.)

Originating Site Facility Fee - *Carriers and Intermediaries*

To receive the facility payment, submit claims with HCPCS code "Q3014, telehealth originating site facility fee"; short description "telehealth facility fee." The type of service for the telehealth originating site facility fee is "9, other items and services."

By submitting "Q3014" HCPCS code, the originating site authenticates they are located in either a rural HPSA or non-MSA county.

The facility fee will be updated yearly based upon the Medicare economic index and will be announced in an annual PM for carriers and intermediaries. Carriers and intermediaries must use these fees to pay the correct amount for this service. The Medicare physician fee schedule database will indicate that this claim is carrier-priced. This process is similar to the process currently used for the payment of certain mammography services.

Physicians' and practitioners' offices must bill the appropriate Medicare carrier for the originating site facility fee.

Intermediary claims processing. The appropriate bill types for this benefit are: 12X, 13X, 71X, 73X, and 85X. The originating site can be located in a number of revenue centers within a facility, such as an emergency room (450), operating room (360), or clinic (510). Instruct your providers to report this service under the revenue center where the service was performed and include HCPCS code "Q3014, telehealth originating site facility fee."

Note that the originating site facility fee is a Part B payment. Pay the originating site facility fee outside of current fee schedules or other payment methodologies (e.g., payment must be made in addition to the DRG, outpatient prospective payment system.) (See "Originating site facility fee payment methodology".)

Hospitals and critical access hospitals bill their intermediary for the originating site facility fee. Independent and provider-based RHCs and FQHCs bill the appropriate intermediary using the RHC or FQHC bill type and billing number. HCPCS code "Q3104, telehealth originating site facility fee" is the only non-RHC/FQHC service that is billed using the clinic/center bill type and provider number. For all other non-RHC/FQHC services, provider based RHCs and FQHCs must bill using the providers bill type and billing number. Independent RHCs and FQHCs must bill the carrier for all other non-RHC/FQHC services.

If an RHC/FQHC visit occurs on the same day as a telehealth service, the RHC/FQHC serving as an originating site must bill for HCPCS code "Q3014 telehealth originating site facility fee" on a separate revenue line from the RHC/FQHC visit.

The telehealth professional service payment and originating site facility fee are subject to post payment verification.

Carrier Editing of Telehealth Claims

Carriers must install edits effective for dates of service October 1, 2001, and later to ensure that only providers approved to bill for these telehealth services are paid. Use the following information to develop edits for telehealth claims:

Professional Service

When the "GT" modifier or the "GQ" modifier is billed for dates of service October 1, 2001, and later with CPT codes 99241 - 99275, 99201 - 99215, 90804 - 90809, or 90862; process the claim only when the physician or practitioner is licensed to provide the service under State law. Carriers must review the State licensure provisions of States for which they process claims, and disallow any claims from practitioners who are not authorized the applicable covered telehealth service under State law. For example, if a nurse practitioner is not licensed to provide individual psychotherapy under State law, he or she would not be permitted to receive payment for individual psychotherapy under Medicare.

If a carrier receives professional claims with the "GQ" modifier representing "via asynchronous telecommunications system", deny claims from physicians or practitioners who are not affiliated with a Federal telemedicine demonstration conducted in Alaska or Hawaii. Carriers may require the physician or practitioner at the distant site to document his or her participation in a Federal telemedicine demonstration program conducted in Alaska or Hawaii prior to paying for telehealth services provided via asynchronous, store and forward technologies.

For services for which claims are denied because the provider may not bill for the service, use MSN message 21.18: "This item or service is not covered when performed or ordered by this practitioner." Carriers must use remittance advice message 52 when denying the claim based upon MSN message 21.18.

If professional service codes are submitted with one of the telehealth modifiers and the service is not considered a consultation, office or other outpatient visit, individual psychotherapy or pharmacologic management use MSN message 9.4: "This item or service was denied because information required to make payment was incorrect. Remittance advice message depends on what is incorrect, e.g., B18 if procedure code or modifier is incorrect, 125 if submission billing error, 4-12 for difference inconsistencies." Carriers must use B18 as the explanation for the denial of the claim.

Enrollment

This PM does not affect Medicare enrollment. The physician or practitioner at the distant site and the originating site facility are not subject to separate enrollment procedures for telehealth.

The *effective date* for this PM is October 1, 2001

The *implementation date* for this PM is October 1, 2001

These instructions should be implemented within your current operating budget.

This PM may be discarded after May 1, 2002.

If you have any questions, contact your regional office.

Federal Register

Thursday,
November 1, 2001

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 405 et al.

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule

[Federal Register: November 1, 2001 (Volume 66, Number 212)]
[Rules and Regulations]
[Page 55245-55294]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr01no01-21]

[[Page 55245]]

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

----

42 CFR Part 405 et al.

Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Final Rule

[[Page 55246]]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, and 415

[CMS-1169-FC]
RIN 0938-AK57

Medicare Program; Revisions to Payment Policies and Five-Year

Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period makes several changes affecting Medicare Part B payment. The changes affect: refinement of resource-based practice expense relative value units (RVUs); services and supplies incident to a physician's professional service; anesthesia base unit variations; recognition of CPT tracking codes; and nurse practitioners, physician assistants, and clinical nurse specialists performing screening sigmoidoscopies. It also addresses comments received on the June 8, 2001 proposed notice for the 5-year review of work RVUs and finalizes these work RVUs. In addition, we acknowledge comments received on our request for information on our policy for CPT modifier 62 that is used to report the work of co-surgeons. The rule also updates the list of certain services subject to the physician self-referral prohibitions to reflect changes to CPT codes and Healthcare Common Procedure Coding System codes effective January 1, 2002. These refinements and changes will ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 modernizes the mammography screening benefit and authorizes payment under the physician fee schedule effective January 1, 2002; provides for biennial screening pelvic examinations for certain beneficiaries effective July 1, 2001; provides for annual glaucoma screenings for high-risk beneficiaries effective January 1, 2002; expands coverage for screening colonoscopies to all beneficiaries effective July 1, 2001; establishes coverage for medical nutrition therapy services for certain beneficiaries effective January 1, 2002; expands payment for telehealth services effective October 1, 2001; requires certain Indian Health Service providers to be paid for some services under the physician fee schedule effective July 1, 2001; and revises the payment for certain physician pathology services effective January 1, 2001. This final rule will conform our regulations to reflect these statutory provisions.

In addition, we are finalizing the calendar year (CY) 2001 interim RVUs and are issuing interim RVUs for new and revised procedure codes for calendar year (CY) 2002. As required by the statute, we are announcing that the physician fee schedule update for CY 2002 is -4.8 percent, the initial estimate of the Sustainable Growth Rate (SGR) for CY 2002 is 5.6 percent, and the conversion factor for CY 2002 is $36.1992.

practitioners, we believe the average practice expense per hour for all physicians is sufficient to use in the practice expense methodology.

Result of Evaluation of Comments

The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the rate for CPT code 97802. We are also changing the payment rate for CPT code 97804 using the assumption that the code will normally be billed for 4 to 6 patients with the average of 5. Using these revised values, the payment rate for group medical nutrition therapy will approximate the hourly rate paid for other medical nutrition therapy services.

F. Telehealth Services

Beginning October 1, 2001, the BIPA amended section 1834 of the Act to specify that we pay a physician (as defined in section 1861(r) of the Act) or a practitioner (described in section 1842(b)(18)(C) of the Act) for telehealth services that are furnished via a telecommunications system to an eligible telehealth individual.

The BIPA defined Medicare telehealth services as professional consultations, office or other outpatient visits, and office psychiatry services identified as of July 1, 2000, by CPT codes 99241 through 99275; 99201 through 99215, 90804 through 90809 and 90862 (and as we may subsequently modify) and any additional service we specify. The BIPA defines an eligible telehealth individual as an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Section 1834(m) of the Act, as added by the BIPA, limited an originating site to a physician's or practitioner's office, hospital, critical access hospital, rural health clinic, or Federally qualified health center. Additionally, the BIPA specified that the originating site must be located in one of the following geographic areas:

• In an area that is designated as a rural health professional shortage area (HPSA) under section 332(a)(1)(A) of the Public Health Service Act.

• In a county that is not included in a Metropolitan Statistical Area (MSA).

However, an entity participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from us as of December 31, 2000 would not be required to be in a rural HPSA or non-MSA.

The BIPA also required that we pay a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth beneficiary an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

This section also provided for a facility fee payment for the period beginning October 1, 2001 through December 31, 2002, to the originating site of $20. For each subsequent year, the facility fee for the preceding year is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The BIPA also amended section 1833(a)(1) of the Act to specify that the amount paid must be 80 percent of the lesser of the actual charge or the amounts specified in new section 1834(m)(2) of the Act.

In order for us to have this benefit expansion implemented timely, we have used a program memorandum. The program memorandum was effective October 1, 2001. This final rule will be effective January 1, 2002.

The rule published on August 2, 2001 proposed to establish policies for implementing the provisions of section 1834(m) of the Act, as added by the BIPA, that change Medicare payment for telehealth services.

We proposed to revise § 410.78 to specify that Medicare beneficiaries are eligible for telehealth services only if they receive services from an originating site located in either a rural HPSA as defined by section 332(a)(1)(A) of the Public Health Services Act or in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

1. Definitions

Section 1834(m)(4)(F) of the Act, which was added by the BIPA and became effective for services beginning October 1, 2001, defined telehealth services as professional consultations, office and other outpatient visits, individual psychotherapy, pharmacologic management, and any additional service we specify. Additionally, this provision identified covered services by HCPCS codes identified as of July 1, 2000. We proposed to revise § 410.78 to implement this coverage expansion to include the following services (and corresponding CPT codes):

• Consultations (codes 99241 through 99275).

• Office and other outpatient visits (codes 99201 through 99215).

• Individual psychotherapy (codes 90804 through 90809).

• Pharmacologic management (code 90862).

We solicited comments regarding the guidelines that we should use to make additions or deletions of services. We also solicited comments about specific services that may be appropriate to be covered under the Medicare telehealth benefit.

In this final rule, we are specifying at § 410.78 that, except for the use of store and forward technology in the demonstration programs conducted in Alaska or Hawaii, an interactive telecommunications system must be used and the medical examination of the patient must be at the control of the physician or practitioner at the distant site. We are defining interactive telecommunications system as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and physician or practitioner at the distant site. We are also specifying that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

A patient need not be present for a Federal telemedicine demonstration program conducted in Alaska or Hawaii. We are specifying that for Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system. Additionally, we are specifying that the physician or practitioner at the distant site must be affiliated with the demonstration program.

We are defining asynchronous, store and forward technologies, as the transmission of the patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patient's medical condition and adequate for rendering or confirming a diagnosis or treatment plan. Finally, we are defining the originating site as the location of an eligible telehealth individual at the time the service being furnished via a telecommunications system occurs.

2. Conditions of Payment

The BIPA changed the telepresenter requirements. In accordance with section 1834(m)(2)(C) of the Act, a

telepresenter is not required to be present. Therefore, we would not require a telepresenter as a condition of Medicare payment.

Section 1834(m)(1) of the Act requires that Medicare make payments for telehealth services furnished via a telecommunications system by a physician or a practitioner (described in section 1842(b)(18)(C) of the Act). Non-physician practitioners described in this section of the Act include nurse practitioners, physician assistants, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, and certified registered nurse anesthetists or anesthesiologists' assistants. Section 1834(m)(2) of the Act specifies that we pay the physician or practitioner at the distant site who furnishes a telehealth service an amount equal to the amount that the physician or practitioner would have been paid under Medicare had the service been furnished without the use of a telecommunications system.

Certified registered nurse anesthetists and anesthesiologists' assistants would not be permitted to bill for and receive payment for a telehealth service under this provision. Under the Medicare program, these practitioners do not receive payment for office visits, consultation, individual psychotherapy, or pharmacologic management when these services are furnished without the use of a telecommunications system. Section 1834(m)(2) of the Act specifies that we pay to the distant site physician or practitioner an amount equal to what would have been paid for the service without the use of a telecommunications system. Therefore, certified registered nurse anesthetists and anesthesiologists' assistants would not receive payment for telehealth services.

We proposed at § 410.78 that, as a condition of Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under State law.

Section 1834(m)(2)(A) of the Act specifies that the payment amount for the professional service is equal to the amount that would have been paid without the use of a telecommunications system. Medicare payment for physicians' services is generally based, under section 1848 of the Act, on the resource-based physician fee schedule. Payment to other health care practitioners listed earlier, authorized under section 1833 of the Act, is based on a percentage of the physician fee schedule payment amount. Therefore, we will pay for office or other outpatient visits, consultation, individual psychotherapy, and pharmacologic management services furnished by physicians at 80 percent of the lower of the actual charge or the fee schedule amount for physicians' services. We will also pay for services furnished by other practitioners at 80 percent of the lower of the actual charge or that practitioner's respective percentage of the physician fee schedule.

Section 1834(m)(2) of the Act provides for a professional fee for the physician or practitioner at the distant site (equal to the applicable Part B fee schedule amount) and a $20 facility fee for the originating site. Telepresenters are not required, unless one is deemed medically necessary by the physician or practitioner at the distant site. The BIPA does not address the issue of payment for the telepresenter. The Office of the Inspector General has advised us that permitting the physician or practitioner at the distant site to pay the telepresenter creates a significant risk under the anti-kickback statute. Therefore, we establish in § 414.65 that payments made to the distant site physician or practitioner for professional fees, including deductible and coinsurance (for the professional service), are not to be shared with the referring practitioner or telepresenter.

However, the telepresenter could bill and receive payment for services that are not telehealth services that a telepresenter would otherwise be allowed to provide under the Medicare statute, including services furnished on the same day as the telehealth service.

The BBA prohibited any payment for line charges or facility fees associated with a professional consultation via a telecommunications system. Section 1834(m)(2)(B) of the Act, as added by the BIPA, provides for a facility fee payment to the originating site, specifying that the amount of payment is 80 percent of the lesser of the actual charge or a facility fee of $20.00. The BIPA further specifies that, beginning January 1, 2003, the originating facility fee be increased annually by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. Additionally, we clarify that the Geographic Practice Cost Index (GPCI) would not apply to the facility fee for the originating site. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician's fee schedule. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance. We would revise § 414.65 to provide for payment of a facility fee to the originating site.

Section 1834(m)(3) of the Act specifies that sections 1842(b)(18)(A) and (B) apply to physicians and practitioners receiving payment for telehealth services and to originating sites receiving a facility fee, in the same manner as they apply to practitioners. This section requires that payment for such services may only be made on an assignment-related basis. We did not reflect this provision in the proposed rule. Because this requirement is specified in the BIPA and we have no discretion, we are implementing it in this final rule in new § 414.65(d).

Comment: One commenter believed that requiring an originating site to be located in a rural HPSA or non-MSA county would not permit medical practitioners located in urban and suburban areas to offer telehealth services.

Response: We clarify that, as a condition of payment under Medicare, the originating site must be located in a rural HPSA or non-MSA county. The physician or practitioner at the distant site, who provides the telehealth service, is not subject to these limitations. For example, a psychologist in Salt Lake City, Utah would be able to provide a mental health visit to a beneficiary at a physician's office located in a non-MSA county.

Comment: We received various comments on the definition of an originating site. Many commenters believe that the list of facilities eligible to be a telehealth originating site should be expanded beyond those specified in the statute. Specific suggestions were received to include the patient's residence, skilled nursing facilities, nursing homes, and community mental health centers as originating site facilities within this provision. Another commenter suggested that we recommend legislative changes to remove the requirement that an originating site facility be located in a HPSA or non-MSA county.

Moreover, one organization requested that all locations included within the Alaska Native Tribal Health Consortium, including but not limited to outpatient health facilities recognized by the Indian Health Service as tribal health facilities be included as an originating site. The commenter requested that these sites be defined as an originating site regardless of whether they are certified as a Medicare Federally qualified health center or not.

Response: Section 1834(m) of the Act defines an originating site facility to include only a physician's or practitioner's office, hospital, critical access hospital, rural health clinic or Federally qualified health center.

Further, the Act specifies that the originating site must be located in a rural HPSA or non-MSA county. We do not have the legislative authority to expand the definition of a telehealth originating site beyond this provision. However, we will be studying this issue as part of a report to the Congress as authorized by section 223(d) of the BIPA.

Comment: One specialty college requested confirmation that the patient's medical information provided via store and forward telehealth is furnished to the physician or practitioner at the distant site in order to recommend or confirm a diagnosis and or treatment plan and not to provide a formal interpretation of imaging exams.

Response: The commenter is correct. Payment for services via store and forward technology under this provision does not include formal interpretation of an imaging exam. Medicare currently allows coverage and payment for medical services delivered via a telecommunications system that do not require a face-to-face ''hands on'' encounter. Section 2020(A) of the Medicare Carriers Manual addresses this issue and lists radiology, electrocardiogram, and electroencephalogram interpretations as examples of such services.

Comment: In the proposed rule, we requested comments on the guidelines that we should use to make additions or deletions to covered Medicare telehealth services. We also requested suggestions and comments about specific services that may be appropriate for payment under the Medicare telehealth benefit. In response to our solicitation, we received one comment regarding the guidelines we should use to make changes to the scope of Medicare telehealth coverage. Ten commenters provided specific suggestions regarding additional services that may be appropriate for the Medicare telehealth benefit.

Several commenters indicated that a psychiatric diagnostic interview, CPT code 90801, would be appropriate for Medicare telehealth payment. One association stated that the elements of this service are directly comparable to a new patient office visit, which the law defines as a telehealth service. Given that the law permits us to add additional services as appropriate, this commenter suggested that we include a psychiatric diagnostic interview within the definition of a telehealth service. Another association suggested that interactive psychotherapy, CPT codes 90810, 90812 and 90814, should be covered Medicare telehealth services. Interactive psychotherapy uses play equipment, physical devices and other mechanisms of non-verbal communication in an office or outpatient facility.

Several commenters suggested that telerehabilitation interventions that provide education, mentoring and consultation be included within the scope of Medicare telehealth coverage. The commenters specifically note that speech therapy and physical and occupational therapy should be included as telehealth services.

One consortium requested that all services provided under the Federal telehealth project in Alaska be included as covered telehealth services within this provision. The commenter believes that virtually all evaluation & management and psychiatry services should be included as Medicare telehealth services. Additionally, the commenter notes that many respiratory, digestive, ophthalmology and otorhinolaryngology services are appropriate for telehealth coverage.

One organization suggested that we consider guidelines similar to those currently in place for non-telehealth services. For instance, the commenter stated the service should be reasonable and necessary, safe and effective, medically appropriate, and provided within the purview of accepted standards of medical practice. The commenter stresses that the type of technology used to deliver the service should be secondary to the reasonable and necessary criteria.

Response: We will use these comments and suggestions to assist us in establishing guidelines for a telehealth coverage process and the addition of specific telehealth services that may be appropriate for Medicare beneficiaries. However, we do not believe it would be appropriate to expand the scope of telehealth services beyond the services explicitly listed in the Act until we have a process in place for adding new telehealth services.

Comment: With regard to the definition of a ''telecommunications system'', one organization encouraged us to permit store and forward technologies in other circumstances beyond federal telemedicine demonstration projects conducted in Alaska or Hawaii. The commenter believes that emphasis should be given to whether a particular service is reasonable and necessary rather than specific technology requirements. Moreover, the commenter stated that the face-to-face requirement is outdated for telehealth as well as other areas of the Medicare fee schedule and suggested that current technology, such as electronic mail, permits physicians to care for their patients even when the patient is not present.

Response: Section 1834(m) of the Act defines a telehealth service as office and other outpatient visits (99201 through 99215), professional consultations (99241 through 99275), individual psychotherapy (90804 through 90809), and pharmacologic management (90862). Further, the law specifies that payment must be equal to what would have been paid without the use of a telecommunications system.

As a condition of payment under Medicare, these services require a face-to-face patient encounter. We believe that the patient's presence and use of an interactive audio and video telecommunications system permitting the distant site practitioner to interact with the patient provides a reasonable substitute for a face-to-face encounter. The law provides for the use of asynchronous, store and forward technologies for delivering telehealth services only for telemedicine demonstration projects conducted in Alaska or Hawaii. We do not have the authority to expand the use of store and forward technology in delivering telehealth services.

Comment: One organization in a remote region requested that a definition of a telepresenter be added to § 410.78. The commenter suggested we permit a certified community health aid to present a patient when the aide is the only medical professional available to act as a telepresenter.

Response: The physician or practitioner at the distant site has the authority to determine whether it is medically necessary to require a telepresenter and, if necessary, the appropriate medical professional needed to present the patient. We do not believe it is appropriate for us to specify the type of medical professionals that are necessary to act as a telepresenter.

Comment: We received conflicting comments concerning interstate telehealth services. One organization requested that we require the physician or practitioner at the distant site to be licensed in the State where the originating site is located. On the other hand, an association requested clarification that the physician or practitioner at the distant site only needs to be licensed in the State where he or she is located and does not need to be licensed in the State where the originating site is located. Another commenter requested that we clarify that the service is considered rendered where the distant site physician or practitioner is located.

Response: We defer to State law regarding licensure issues. When the

State law for the originating site permits an out-of-State practitioner to provide a telehealth service, without being licensed in the State in which the originating site is located, Medicare would make payment for the telehealth service. However, when State law precludes an out-of-State practitioner from delivering a telehealth service, Medicare would not pay for that service.

We clarify that for payment purposes, the site of service for the telehealth service is the location of the physician or practitioner at the distant site. Given that section 1834(m) of the Act specifies that payment to the physician or practitioner at the distant site must be equal to the amount that would have been paid without the use of telehealth, it is appropriate to use the Geographic Practice Cost Index (GPCI) relevant to the distant site. However, our determination of the distant site physician's or practitioner's location as the site of service for Medicare payment is not intended to make a comment regarding the scope of medical practice.

Comment: One consortium believes that the proposed rule would not permit the physician or practitioner at the distant site to bill for a telehealth service when State or Federal law exempts a physician or practitioner from being licensed in the State in which he or she is currently employed. The consortium is a Federal telemedicine demonstration project that would be permitted to use store and forward telecommunications technologies in delivering telehealth services. The commenter notes that the State of Alaska exempts physicians or practitioners who are part of the military or Public Health Service that provide health care services in Alaska from its licensure requirements. Further, the commenter stated that Federal law authorizes health care professionals who are members of the military providing services for the Department of Defense to practice in any State provided the professionals are licensed in a State, the District of Columbia or other specific locations. The commenter also noted that current Medicare manual instructions specify that when a physician in a Federal hospital provides services to the public generally as a community institution, he or she may be considered as meeting the statutory definition of a physician even though he or she may not have a license to practice in the State in which he or she is employed.

Response: The telehealth provision does not affect State or Federal legislation providing certain physicians or practitioners an exemption from State licensure. When Federal or State law exempts a physician or practitioner from State licensure, then the physician or practitioner at the distant site is permitted to provide a telehealth service regardless of whether he or she is licensed within the State where he or she is employed.

Comment: One organization requested that § 414.65(a)(2) be revised to specify for what services the physician or practitioner who presents the patient could bill. The commenter believes that when the physician at the distant site determines that it is medically necessary for another practitioner to assist in providing the telehealth service, the telepresenter should be compensated. The commenter suggested that a telepresenter be permitted to bill for a consultation or confirmatory consultation.

Response: On the day the telehealth service occurs, the telepresenter may bill and receive payment for services that are not telehealth services that he or she would otherwise be allowed to provide under Medicare. A telepresenter, for example, a nurse practitioner, could bill for and be paid for a medically necessary office, outpatient or inpatient visit preceding or subsequent to a telehealth service. Additionally, the telepresenter could be paid for other medically necessary services requested by the physician or practitioner at the distant site. However, the physician at the distant site may not share any portion of the telehealth payment with the telepresenter or referring practitioner. We do not agree that § 414.65(a)(2) should be changed to specify the services for which a telepresenter can and cannot bill. This section implements payment for telehealth services only, and the Act does not provide for a payment to the telepresenter for telehealth services.

Comment: Many organizations and individual commenters expressed overall support for the revision of Medicare payment for telehealth. Specifically, commenters mentioned removal of the fee sharing requirement, relaxed conditions of payment, and the addition of non-MSA counties to the geographic areas eligible for telehealth under Medicare. The commenters noted that these changes will have a positive effect on health care delivery and will help provide services to areas where specialty care is sparse.

Response: We agree that the proposed revisions to Medicare telehealth coverage and payment policies, as authorized by the BIPA, remove significant barriers for physicians and practitioners wishing to provide telehealth services.

Comment: One commenter indicated that the cost of collecting the coinsurance for the originating site facility fee could easily exceed the amount the facility would collect from the beneficiary. The commenter encouraged us to permit originating sites to waive the coinsurance in those situations where the telehealth facility charge is the only amount to be billed to the beneficiary.

Response: We do not have the authority to eliminate the coinsurance requirement outright for telehealth originating sites. However, Medicare permits the waiver of coinsurance for limited situations. Section 5220 of the Medicare Carriers Manual specifies that physicians and suppliers may waive billing for or collection of coinsurance or deductibles for indigent patients or when the physicians' or suppliers' cost of billing or collecting exceeds or is disproportionate to the amounts to be collected. Documentation must be sufficient to support that costs for billing the beneficiary exceed or are disproportionate to the amount collected from the beneficiary. In this instance, the amount collected refers to 20 percent of the originating site telehealth facility fee.

We clarify that when the patient owes additional coinsurance to the originating site for other Medicare services, billing for the telehealth facility fee coinsurance amount may be consolidated with the coinsurance amount owed for those services. We believe that this would resolve the commenter's concern that the cost for billing and or collecting the coinsurance for a single facility fee could exceed or be disproportionate to the amount collected from the beneficiary.

Comment: One association submitted a number of comments that have payment implications for the Federally qualified health center benefit.

Response: These issues involve specific aspects of the Federally qualified health center payment methodology and are beyond the scope of this provision. We will take these comments into consideration in formulating future instructions for payment implications on FQHCs.

Result of Evaluation of Comments

We are implementing this provision as stated above.

G. Indian Health Service

The Indian health care system provides primary health care to many American Indian and Alaska Native Medicare beneficiaries. This system consists of programs operated by a Federal agency, the Indian Health

(b) * * *

(1) *General rule.* Except as specified in paragraphs (b)(2) and (b)(3) of this section, payment may be made for a pelvic examination performed on an asymptomatic woman only if the individual has not had a pelvic examination paid for by Medicare during the preceding 23 months following the month in which her last Medicare-covered screening pelvic examination was performed.

(2) *More frequent screening based on high-risk factors.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner specified in paragraph (a) of this section, 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, as determined in accordance with the following risk factors:

* * * * *

(3) *More frequent screening for women of childbearing age.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term ''woman of childbearing age'' means a woman who is premenopausal, and has been determined by a physician, or a qualified practitioner, as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.

* * * * *

9. Section 410.78 is revised to read as follows:

§ 410.78 Office and other outpatient visits, consultation, individual psychotherapy and pharmacologic management via an interactive telecommunications system.

(a) *Definitions.* For the purposes of this section the following definitions apply:

(1) *Asynchronous store and forward technologies* means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) *Distant site* means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(4) *Originating site* means, for purposes of a consultation, office or other outpatient visit, individual psychotherapy, or pharmacologic management via an interactive telecommunications system, the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) *General rule.* Medicare Part B pays for office and other outpatient visits, professional consultation, individual psychotherapy, and pharmacologic management furnished by means of an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to provide the service under State law. When the physician or practitioner at the distant site is licensed under State law to provide a covered telehealth service (that is, professional consultations, office and other outpatient visits, individual psychotherapy, and pharmacologic management), he or she may bill for, and receive payment for, this service when delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as described § 410.74.

(iii) A nurse practitioner as described in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as described in § 410.77.

(vi) A clinical psychologist as described in § 410.71.

(vii) A clinical social worker as described in § 410.73.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(4) Originating sites must be located in either a rural health professional shortage area as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) or in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act. Entities participating in a Federal telemedicine demonstration project that have been approved by, or receive funding from, the Secretary as of December 31, 2000 qualify as an eligible originating site regardless of geographic location.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitation.* A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may

not seek payment for medical evaluation and management services.

10. A new subpart G is added to read as follows:

Subpart G—Medical Nutrition Therapy

Sec.
410.130 Definitions.
410.132 Medical nutrition therapy.
410.134 Provider qualifications.

Subpart G—Medical Nutrition Therapy

§ 410.130 Definitions.

For the purposes of this subpart, the following definitions apply:

Chronic renal insufficiency means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 13–50 ml/min/1.73m^2).

Diabetes means diabetes mellitus consisting of two types. Type 1 is an autoimmune disease that destroys the beta cells of the pancreas, leading to insulin deficiency. Type 2 is familial hyperglycemia that occurs primarily in adults but can also occur in children and adolescents. It is caused by an insulin resistance whose etiology is multiple and not totally understood. Gestational diabetes is any degree of glucose intolerance with onset or first recognition during pregnancy. The diagnostic criterion for a diagnosis of diabetes for a fasting glucose tolerance test is greater than or equal to 126 mg/dL.

Episode of care means services covered in a 12-month time period when coordinated with initial diabetes self-management training (DSMT) and one calendar year for each year thereafter, starting with the assessment and including all covered interventions based on referral(s) from a physician as specified in § 410.132(c). The time period covered for gestational diabetes extends only until the pregnancy ends.

Medical nutrition therapy services means nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action (including a physician within the meaning of section of 1101(a)(7) of the Act).

Renal disease means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant.

Treating physician means the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.

§ 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols.

(b) *Limitations on coverage of MNT services.*

(1) MNT services based on a diagnosis of renal disease as described in this subpart are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act.

(2) A beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination process.

(3) In years when the beneficiary is eligible for MNT and follow-up DSMT, the beneficiary may only receive the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the national coverage determination process.

(4) If a beneficiary has both diabetes and renal disease, the beneficiary may only receive the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater.

(5) An exception to the maximum number of hours in (b)(2), (3), and (4) of this section may be made when the treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals.* Referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation maintained by the referring physician in the beneficiary's medical record. Referrals must be made for each episode of care and any additional assessments or interventions required by a change of diagnosis, medical condition, or treatment regimen during an episode of care.

§ 410.134 Provider qualifications.

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. ''Registered dietitian or nutrition professional'' means an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(c) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) of this section.

(d) *Exceptions.*

(i) A dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required to meet the requirements of (a) and (b) of this section.

(ii) A ''registered dietician'' in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) of this section.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 411.15, paragraph (a)(1) is revised, and a new paragraph (k)(10) is added to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(a) * * *

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic examinations, prostate cancer screening