

Medicare State Operations Manual Provider Certification

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

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NEW/REVISED MATERIAL--EFFECTIVE DATE: January 9, 2001

Section 2080, Hospice – Citations and Description, is revised to delete a sentence which was inadvertently included in Revision I of the manual.

Section 2250, Community Mental Health Centers (CMHC) – Citations and Description is revised. The material regarding certification procedures and guidelines for CMHCs, revises procedures for approving CMHC's seeking Medicare approval and changing ownership. The procedures also formalize the use of an onsite visit to CMHCs to ensure that Federal participation requirements are met. In addition, the revision includes the contents of various policy memoranda in use concerning CMHCs.

Exhibit 275, Attestation Statement, CMHCs must use this form to attest that they meet the requirements in the Social Security Act and the HCFA Regulations.

Exhibit 276, Provider Agreement, an agreement between the Secretary of Health and Human services and the CMHC that the CMHC signs agreeing to conform to the provisions of the Social Security Act and the HCFA Regulations.

Exhibit 277, Fiscal Intermediary Medicare Provider Billing number Deactivation Letter Used by FI, is sent to the CMHC letting the facility know that there has been no claims under Medicare submitted and that they are no longer an active Medicare Provider.

Exhibit 278, Model Denial Letter for CMHC Applicants—State Restrictions on Screening, is used to inform the CMHC that the facility does not meet the screening requirements for Medicare certification.

Exhibit 279, Model Letter, Notice of Findings of Non-Compliance, is used to notify the CMHC that it does fails substantially to meet the applicable provisions of the Social Security Act and HCFA Regulations and/or fails to comply with the Provider Agreement.

Exhibit 280, Model Letter, Notice of Termination of Provider Agreement, is sent to the CMHC notifying it that it does not meet the CMHC requirements and will be terminated.

Exhibit 281, Model Letter, CMHC That Has Ceased Operating, is sent to the CMHC notifying it that HCFA has determined that the facility was closed and the Provider Agreement will be terminated.

Exhibit 282, Model Letter, Participation in Medicare as a CMHC Providing Partial Hospitalization Services (Including Threshold and Service Requirements), is sent to the CMHC explaining the requirements needed to be met to be certified as a CMHC providing partial hospitalization services.

Exhibit 283, Model Letter, Notice of Failure to Meet Threshold and Service Requirements, is sent to the CMHC informing it that it does not meet the requirements to participate in the Medicare Program as a CMHC providing partial hospitalization services.

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

- o Homemaker services;
- o Medical supplies (including drugs and biologicals) and the use of medical appliances related to the terminal diagnosis;
- o Short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in a Medicare/Medicaid approved inpatient facility; and
- o Continuous home care provided for a period of 8 or more hours in a day during a period of crisis, and only as necessary to maintain the patient at home.

In addition, the statute stipulates other specific requirements including a limitation on the proportion of inpatient days for hospice patients and a prohibition against discontinuing or diminishing services for Medicare beneficiaries unable to pay for hospice care.

Hospices must maintain professional management and financial responsibility for services provided under arrangements, regardless of the location or facility in which such services are furnished.

If a hospice is established by an entity which participates in the Medicare program as another type of provider (hospital, SNF, HHA), the SA should attempt to coordinate simultaneous certification surveys of these entities, i.e., for compliance with hospice CoPs and for compliance with the other appropriate CoPs.

NOTE: Section 1861(dd)(4)(A) of the Act states that if a hospice is approved as being part of another type of provider, with a separate provider number, it shall be considered to meet those CoPs that are common to both the hospice and the other type of provider.

2081. HOSPICE - MULTIPLE LOCATIONS

Neither the statute nor the hospice regulations provides for establishing hospice "satellite" offices. Nonetheless, a hospice is not precluded from providing services at more than one location if certain requirements assuring quality of care are met and these locations are approved by the RO. The RO, in order to support HCFA's responsibility to protect the Medicare trust fund against excessive and unnecessary costs, will also ensure that the locations promote cost effective health care. This includes reimbursing hospices at a rate that has been established for the local area. The RO will make a final determination on both quality and cost effectiveness issues with the assistance of the State agency and the fiscal intermediary, if necessary, and will notify all parties of its decision.

To support our concern for quality, HCFA requires a hospice who provides services at more than one location, to comply with the following:

- o The hospice must be able to exert the supervision and control necessary at each location to assure that all hospice care and services continue to be responsive to the needs of the patient/family at all times and in all settings. Hospice care requires the closest of interventions and a distant "parent" cannot provide the immediate access needed to ensure health and safety.
- o Each location must provide the same full range of services that is required of the hospice issued the provider number;
- o Each location must be responsible to the same governing body and central administration that governs the hospice issued the provider number, and the governing body and central administration must be able to adequately manage the location and assure quality of care at the location; and

o All hospice patients' clinical records requested by the surveyor must be available at the hospice site issued the provider number.

If a proposed hospice location does not meet the above criteria for quality and cost effectiveness, it must seek Medicare approval as a separate hospice with its own provider agreement and provider number.

If the hospice does operate at multiple locations, a deficiency found at any location will result in a compliance issue for the entire hospice.

2082. ELECTION OF HOSPICE BENEFIT BY RESIDENT OF SNF, NF, ICF/MR, OR NON-CERTIFIED FACILITY

There is no indication in the statute that the term "home" is to be limited for a hospice patient. A patient's home is where he or she resides. A hospice may furnish routine or continuous home care to a Medicare beneficiary who resides in a SNF, NF, ICF/MR, or any residence or facility not certified by Medicare or Medicaid. The facility is considered to be the beneficiary's place of residence (the same as a house or apartment), and the facility resident may elect the hospice benefit if he/she also meets the hospice eligibility criteria. The hospice then assumes full responsibility for professional management of the individual's hospice care in accordance with the hospice CoPs and makes any arrangements necessary for inpatient care in a participating Medicare or Medicaid facility.

A. Compliance With SNF/NF CoPs.--The SNF/NF CoPs are applicable to all of the residents in a SNF/NF facility. Neither the statute nor the regulations setting out SNF/NF requirements exempt hospice patients in a SNF/NF from those regulations. Sections 1819(c)(4) and 1919(c)(4) provide that a SNF or NF must "establish and maintain identical policies and practices" regarding transfer, discharge, and the provision of covered services under Medicare or Medicaid "for all individuals regardless of source of payment."

Sections 1819 and 1919 of the Act set forth requirements for SNFs and NFs to ensure that these facilities provide quality care and services to their residents. Even though the SNF/NF is the hospice patient's residence for purposes of the hospice benefit, the SNF/NF must still comply with all SNF/NF Requirements for participation in Medicare or Medicaid. This means that the resident must be assessed using the information contained in the Resident Assessment Instrument (RAI) (which includes both the Minimum Data Set (MDS) and the Resident Assessment Protocols (RAPs)), have a plan of care, which, in this case, will be jointly developed with and agreed upon by the hospice, and be provided with all services contained in the plan of care. The plan of care must be consistent with the hospice philosophy of care.

When a resident of a Medicare/Medicaid participating SNF/NF elects the Medicare hospice benefit, the hospice and the SNF/NF must communicate, establish, and agree upon a coordinated plan of care for both providers which reflects the hospice philosophy, and is based on an assessment of the individual's needs and unique living situation in the SNF/NF. The plan of care must be written in accordance with 42 CFR Part 418.58 and include the individual's current medical, physical, psychosocial, and spiritual needs. The hospice must designate an RN from the hospice to coordinate the implementation of the plan of care. (See 42 CFR 418.68(d).)

This coordinated plan of care must identify the care and services which the SNF/NF and hospice will provide in order to be responsive to the unique needs of the patient/resident and his/her expressed desire for hospice care. The plan of care must include directives for managing pain and other uncomfortable symptoms and be revised and updated as necessary to reflect the individual's current status.

- o Copies of advertisements for recruiting hires; and
- o Results of personal interviews with potential hires.

D. Monitoring Waivers.--The SA monitors the expiration dates of waivers. When the expiration date of an RHC's waiver is imminent, the SA must contact the RHC to determine whether the RHC will be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver.

If it is determined that the RHC will not be in compliance with 42 CFR Part 491.8 as of the expiration date of the waiver, the SA notifies the RHC that it will be terminated from the Medicare program. The RHC should be given notice of the termination at least 15 days before the effective date of the termination date. The termination date cannot be earlier than the day after the expiration date of the waiver.

If the RHC provides evidence that it has hired the required staff, but the staff will not be available at the clinic until after the expiration date of the waiver, the SA initiates termination action pursuant to §3012. The SA informs the RHC that when it meets the staffing requirement it should notify you immediately.

E. Notification.--Both the SA and the ROs should notify an RHC when an RHC's waiver has been approved and include an explanation of the above termination procedures for expired waivers.

2249. RO NOTIFICATION OF RHC APPROVAL

The RO notifies a facility of its approval or disapproval to participate in the Medicare program not later than 60 days after the date the SA has determined that the facility is or is not in compliance with all the RHC requirements, or the date of the facility's application, whichever is later. The RO sends the notification, as indicated below, to avoid confusion about future billing under Medicare and Medicaid as well as to alert other Federal components that have financial interest in the clinics. See §2784 to determine the effective date of participation.

- o The RO sends a copy of Form HCFA-2007 to the Medicare intermediary which has been designated as the regional fiscal agency and another to the SMA which has billing jurisdiction for RHCs.
- o For provider-based clinics, the RO sends a copy of Form HCFA-2007 to the intermediary who normally services that provider.
- o The RO sends a copy of the letter accepting the clinic's agreement to the Regional Health Administrator, HRSA, so that appropriate notification may be given to components of the PHS engaged in program supporting rural health service activity.

The RO adds the following paragraph to the letter accepting the RHC's agreement:

"Your participation as an RHC under the Medicare program will also be accepted as certification as an RHC under the Medicaid program. If you need information about payment for RHC services under the State plan for medical assistance, contact (name, address, and telephone number of appropriate SMA)."

Community Mental Health Centers

2250. COMMUNITY MENTAL HEALTH CENTERS (CMHC)--CITATIONS AND DESCRIPTIONS

A. General--Section 4162 of P.L. 101-508 (OBRA 1990), amended §1861(ff)(3)(A) and §1832(a)(2)(J) of the Social Security Act (the Act) to include CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective October 1, 1991. The regulations are found at 42 CFR Chapter IV, Parts 400, 410,424 and 489.

B. Special Requirements--Section 1866(e)(2) of the Act and 42 CFR Part 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements, but only with respect to providing partial hospitalization services.

C. Community Mental Health Centers--

1. A CMHC, in accordance with §1861(ff)(3)(B)(ii) of the Act, is an entity that meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and

2. In accordance with §1861(ff)(3)(B)(i) of the Act, §1913 (c)(1) of the Public Health Service Act (PHSA), and 42 CFR Part 410.2, a CMHC must provide all of the following core services to meet the statutory definition of a CMHC. Pursuant to 42 CFR Part 410.110, a CMHC may receive Medicare reimbursement for partial hospitalization services only if it demonstrates that it provides such services. The core services include:

- o Outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of the CMHC's mental health service area who have been discharged from inpatient treatment at a mental health facility;
- o 24 hour-a-day emergency care services;
- o Day treatment, or other partial hospitalization services, or psychosocial rehabilitation services; and
- o Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

D. Partial Hospitalization Program (PHP)--A PHP, for Medicare purposes, is a program that is furnished by a hospital to its outpatients or by a CMHC which provides partial hospitalization services.

E. Partial Hospitalization Services Provided by CMHCs or by Others Under Arrangements with the CMHC--In accordance with 42 CFR Parts 410.2 and 410.43, partial hospitalization services for Medicare purposes, means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and that furnishes services that:

1. Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;
2. Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

3. Include any of the following:

- o Individual and group therapy with physicians or psychologists or other mental health professionals authorized or licensed by the State in which they practice (e.g., licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);
- o Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy must be a component of the physician's treatment plan for the individual;
- o Services of other staff (social workers, trained psychiatric nurses, and others) trained to work with psychiatric patients;
- o Drugs and biologicals that cannot be self-administered and are furnished for therapeutic purposes (subject to limitations specified in 42 CFR Part 410.29);
- o Individualized activity therapies that are not primarily recreational or diversionary. These activities must be individualized and essential for the treatment of the patient's diagnosed condition and for progress toward treatment goals;
- o Family counseling, the primary purpose of which is treatment of the patient's condition;
- o Patient training and education, to the extent that training and educational activities are closely and clearly related to the individual's care and treatment of his/her diagnosed psychiatric condition; and
- o Medically necessary diagnostic services.

NOTE:

Since the word "any" could be misinterpreted, we want to be clear that we would not consider delivery of an instance of any one of these services to itself constitute a covered partial hospitalization service. PHPs are intensive, active treatment programs that offer a combination of services and a multi-disciplinary team approach to address each patient's symptoms and functional level.

4. Are a program comprised primarily of diversionary activity, social activity, or recreation therapy does not constitute a partial hospitalization program;

The following services are excluded from the scope of partial hospitalization services defined in §1861(ff) of the Social Security Act:

- o Services to hospital inpatients;
- o Meals, self-administered medications, transportation; and
- o Vocational training.

F. Definitions of Core Services-- HCFA defines the CMHC core services as follows:

o **Outpatient Services** are separate from partial hospitalization services and contain the elements of diagnosis, treatment, and follow-up (as appropriate). Screening and referral do not constitute the provision of outpatient services.

- Specialized outpatient services to children--In this context, "children" are defined as persons through the age of 21 years.

- Specialized outpatient services to the elderly.--In this context, “elderly” are defined as persons aged 62 years and older.

- Specialized outpatient services to the chronically mentally ill.--Chronic mental illness should be evidenced by a psychiatric diagnosis as defined by the current edition of the American Psychiatric Association’s Diagnostic and Statistical Manual.

- Specialized outpatient services to patients discharged from a mental health facility.--Such services must be supported by evidence of a prior psychiatric inpatient hospitalization.

o **24 hour Emergency Care Services** must be available through a system that provides for access to a clinician and appropriate disposition with follow-up documentation of the emergency in the patient’s CMHC medical record. A psychiatric emergency may occur at any time, and a patient must have access to evaluation and stabilization services after normal business hours. A range of emergency interventions may be necessary and should be available to the patient, including a face-to-face interview, medication evaluation, and hospitalization. While hot lines, beepers and answering services may be facets of emergency services, they may not constitute their totality.

o **Day Treatment or Other Partial Hospitalization Services, or Psychosocial Rehabilitation Services** are structured day programs (less than 24 hours per day) that use a multidisciplinary team approach to develop treatment plans that vary in intensity of services and the frequency and duration of services provided based on the needs of the patient.

Partial hospitalization programs are to provide intensive psychiatric care of an acute nature, utilizing the clinically recognized therapeutic items and services identified in §1861 (ff) of the Act. The treatment program of a PHP is: (1) similar to that of a highly structured, short-term hospital inpatient program; (2) at a level more intense than outpatient day treatment or psychosocial rehabilitation, (3) active treatment that incorporates an individualized treatment plan which describes a coordination of services wrapped around the particular needs of the patient, (4) provided through a multidisciplinary team approach to patient care under the direction of a physician, who certifies the patient’s need for PHP services; (5) the program reflects a high degree of structure and scheduling; (6) in accordance with current practice guidelines, the treatment goals developed for each partial hospitalization patient should be measurable, functional, time-framed, medically necessary, and directly related to the reason for admission. To be covered by Medicare, PHPs must be distinct from other outpatient, day treatment, or psychosocial rehabilitation programs.

The Medicare statutory requirements applicable to PHP are set forth in §1861(ff) of the Act. Based on that section, the term “partial hospitalization services” means the items and services that are prescribed by a physician provided under a program under the supervision of a physician pursuant to an individualized written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate PHP staff), which sets forth the physician’s diagnosis, the type, amount, frequency, and duration of services provided under the PHP treatment plan and the goals for treatment.

o **Screening for Patients Being Considered for Admission to State Mental Health Facilities to Determine the Appropriateness of Such Admission.**--Constitutes the performance of at least one of the steps in a process by which an individual is clinically evaluated, pursuant to State law, for the appropriateness of admission to a State mental health facility by an entity that has both the appropriate clinical personnel, and authorization under State law, to perform all of the steps in the clinical evaluation process except those required to be provided by a 24-hour facility.

NOTE: Some State laws allow only certain entities to perform this type of screening. When a situation is discovered where the State limits screening to specific entities, the RO should discuss the matter with the Regional Attorney before denying entry to the CMHC applicant or terminating existing CMHCs because they are unable to conduct screening because of the State requirements.

o **Core Services Provided Under Arrangement.**-- A CMHC may provide one or more core services under arrangement with another individual, group, or entity only when the following criteria are met:

- **Service Authorized by State Law.**-- In no case may a CMHC provide a service under arrangement when the CMHC has not been given authority to provide the service itself directly under State statute, licensure, certification, or regulation.

- **Full Legal Responsibility.**-- A CMHC that provides a core service under arrangement with another entity remains the legally responsible authority through which comprehensive mental health services are provided. It is not sufficient for the arrangement to be a referral process where the CMHC does not assume overall management responsibility for the provision of core services by a separate individual, group, or entity. The CMHC must retain complete accountability for the services provided under arrangement. The CMHC must retain legal, professional, and administrative responsibility to coordinate care, supervise and evaluate the services, and ensure the delivery of high quality mental health treatment.

- **Written Agreement.**--If a CMHC provides services under arrangement with another party or person, there must be a written agreement or contract between the two parties that specifies the services to be rendered, and the manner in which the CMHC exercises its legal, professional and administrative responsibility for these services. Furthermore, for the agreement to serve as the vehicle through which the CMHC meets the requirement to provide one or more of the core services, the terms of the agreement must be adhered to in practice. The provider's professional supervision over arranged-for services requires application of many of the same quality controls as are applied to services furnished by salaried employees. The provider must accept the patient for treatment in accordance with its admission policies, and maintain a complete and timely clinical record on the patient, which includes diagnoses, medical history, physician's orders, and progress notes relating to all services received, and must maintain liaison with the attending physician regarding the progress of the patient and the need for revised orders. In order to verify the nature of the relationship between the CMHC and the other party, the agreement must be accessible to HCFA or its agents, and the documentation for all services rendered under arrangement must be maintained by the CMHC at the site identified in the provider agreement.

G. **Threshold and Service Requirements for CMHCs.**--The statute requires that an applicant CMHC be providing the core services at the same time of certification, not at some future point in time. Accordingly, HCFA will look for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

o Is fully operational for one entire business quarter;

o Has served, as evidenced by complete, onsite medical record documentation from within 3 months of the date of the initial Medicare application for new applicants or the date of sale for changes of ownership, a sufficient number of persons to enable us to be reasonably assured that the facility is, in fact, complying with basic program requirements. We believe, that to achieve this objective, a facility should have served at least ten non-Medicare patients, including:

- A minimum of three patients for which medical records demonstrate

that the CMHC has:

+ The legal capacity under State law to provide screening services for admission to State mental health facilities,

+ The capability and clinical expertise to provide such screening services; and

+ Provided screening services for the specific purpose (e.g., reason for referral) of which is to assess the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement;

+ A minimum of 3-day treatment or other partial hospitalization or psychosocial rehabilitation patients (this is group treatment and three patients is the smallest number the CMHC could justify as a group); and

+ At least one patient from each of the four outpatient categories:

- children;
- elderly;
- chronically mentally ill; and
- residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility.

NOTE: At this time, there are no prior service requirements regarding the following core service: 24-hour a day emergency care services. However, please be aware that the CMHC must be able to demonstrate that it can provide 24-hour emergency care services. If a CMHC is approved for Medicare participation, it is expected to continue to provide the core services at §1913(c)(1). Providing the services described at §1913(c)(1) of the PHSA is ongoing and not a one time qualifying event for Medicare participation.

2252. CERTIFICATION PROCESS

A. General.-- HCFA ROs are responsible for approving or denying CMHCs for Medicare participation and for notifying CMHCs and the appropriate Fiscal Intermediaries (FI) of the approvals or denials based on the SA certification recommendations, information gained from an onsite visit to the CMHC by a national site visit contractor, and the FI's recommendations as a part of the normal course of CMHC provider enrollment. Therefore, the SA, FI, or national site visit contractor directs all recommendations for approval or denial of the CMHC's request for Medicare participation to the RO, via the SA, following evaluation of the materials submitted with the CMHC's request. As part of the process to approve or deny CMHC applications, ROs are responsible for reviewing the materials collected as the result of the CMHC site visits conducted by the national site visit contractor, including medical records, the completed Site Visit Assessment Tool, and the completed Site Visit Summary. The purpose of the RO's review of these materials is to ensure that CMHC applicants provide the required core services, as well as meet the threshold and service requirements before allowing those applicants to enter into the Medicare program.

B. Request to Participate.--CMHCs that wish to participate in the Medicare program for the purpose of providing partial hospitalization services must request application materials from the SA, and must complete and submit the Form HCFA-855, and a separate statement over a penalty clause attesting that they meet the requirements for CMHCs contained in the Social Security Act and HCFA Regulations (See Exhibit 275).

C. Information to be Sent to CMHC Applicant.--The SA mails copies of the following to applicant CMHCs, including those undergoing a change of ownership:

- o The statutory requirements for CMHCs including the revised PHSA, §1913(c)(1). Also send a copy of the applicable HCFA CMHC regulations.

- o Exhibit 282. Model letter explaining participation in Medicare as a CMHC (including threshold and service requirements). The CMHC's response to this letter serves as its Medicare application.

- o Exhibit 5. Statement of Financial Solvency, Form HCFA-2572.

- Exhibit 131. CMHC Crucial Data Extract (CDE).

- Exhibit 256. Form HCFA-855-Enrollment Application

- Exhibit 276. Provider Agreement

- Exhibit 275. Attestation Statement

D. Processing CMHC Requests, SA Role.--The SA follows these steps when processing applications from CMHCs for Medicare participation and non-assigned provider agreement CMHC changes of ownership. If the provider agreement is not assigned, the new owner can only gain entry into the Medicare program as an initial applicant.

- o The SA forwards concurrently to the appropriate fiscal intermediary, the CMHC's completed Form HCFA-855 along with the CMHC's response to the model letter (application) and a copy of the signed attestation statement. The application must contain at least the following information:

- The name and address of the facility;

- The name of the facility's responsible agent, including the agent's address and telephone number;

- The facility's Medicare provider number, if it is already participating in the Medicare program as a part of another type of provider;
- The identification of all locations where the facility proposes to operate, if it plans to operate at other alternative sites in the community it serves through its provider agreement;
- The Medicare provider number of the other entity, if the facility is operated as part of and under control of another entity that is participating in the Medicare program (provider based);
- The services provided, with the number of full-time equivalent employees;
- The type of ownership or control (i.e., nonprofit, Government);
- A signed attestation statement over a penalty clause (separate from the application) indicating that the facility complies with all of the Federal requirements in §1861(ff) of the Act, the Medicare regulations, and specifically with the requirements contained in §1913(c)(1) of the PHSA;
- A completed and signed Form HCFA-855; and
- A signed Form HCFA-1561, Provider Agreement. (The SA should never indicate or suggest to the CMHC that it is approved and/or that it may begin providing partial hospitalization services to Medicare beneficiaries, because until the RO determines that all requirements are met, it will not sign off on the provider agreement.) The date the RO signs off on the provider agreement will be the CMHC's effective date.

o The SA also forwards the completed package from the national CMHC site visit contractor to the appropriate RO, including the medical records collected at the time of the site visit, the Site Visit Assessment Tool, the Site Visit Summary, and all other completed forms and paperwork.

o In particular, HCFA looks to the SA to evaluate whether the applicant CMHC meets applicable licensing or certification requirements for CMHCs in the State in which it is located, develop any provider based-issues, and comment on the CMHC's plan to operate an alternative site (the proposed alternative site must be a part of the community where the applicant intends to locate the CMHC that is seeking Medicare approval). (See SOM §2252 I.) The SA should also comment on any reason it has to believe or disbelieve that the CMHC applicant is providing the core services or, in change of ownership cases, has moved from its original service area. For example, if the SA knows that State law precludes the CMHC from performing the core service requirement related to screening, it should make the RO aware of this. In fact, if the SA knows that the CMHC does not meet State licensure or certification requirements, it should forward all application materials, including Form HCFA-855, to the RO for a denial of the request to participate in Medicare. The SA will process CMHC certifications pursuant to applicable instructions in SOM §§2760-2776 and the following SOM sections. This includes completing the appropriate blocks of Part I and Part II of the Form HCFA-1539 and completing the CMHC Critical Data Extract based on the information provided by the CMHC.

Should the SA receive any inquiries regarding the site visit by the national site visit contractor or other non-SA role activities, those inquiries should be referred to the appropriate HCFA RO.

E. Processing CMHC Requests, FI Role.--The FI's primary role with respect to CMHC applicants is to verify the information provided on the Form HCFA-855. As a part of the enrollment process, the FI will arrange with the national site visit contractor to evaluate the CMHC's attestation that it provides the core services at §1913(c)(1) of the PHSA by conducting an

unannounced, onsite visit at the site of the applicant CMHC. Also, the FI will contact the RO to verify that the applicant CMHC or CMHC undergoing change of ownership has the legal capacity to provide screening services for admission to State mental health facilities. However, the FI will not request the contractor to conduct an onsite visit until it has completed its review and verified the information provided on the Form HCFA-855, because there is no point in conducting an onsite visit if the CMHC is denied enrollment based on the Form HCFA-855 review, or the CMHC has not provided all of the information necessary to make an enrollment decision. When making an on-site visit, the national site visit contractor will copy medical records to confirm the provision of the core services, record its findings on the CMHC Site Visit Assessment Tool and the CMHC Site Visit Summary and then forward these documents to the SA.

The FI will make a recommendation to the RO, via the SA, of approval or denial of the CMHC's request for Medicare enrollment/participation based on its review of the Form HCFA-855 and the findings of the national site visit contractor resulting from the onsite visit. Neither the FI nor the national site visit contractor should indicate in any way to the CMHC that it may begin to provide partial hospitalization services to Medicare beneficiaries at any point in the enrollment process. The provider's effective date (in the case of approvals), or application denial will be determined by the RO. The SA will ensure that copies of all materials collected as a part of the onsite visit will be submitted to the RO to assist it in its decision. These materials include the completed Site Visit Assessment Tool, medical records, and the CMHC Site Visit Summary. If the FI receives a Form HCFA-855 from the CMHC directly, it should forward the form to the SA for processing as a part of the CMHC application process.

F. Processing CMHC Requests, RO Role.--The RO will adjudicate the CMHC's request to be a provider of partial hospitalization services, or in cases where the CMHC is already in the Medicare program, will determine if the CMHC meets all applicable requirements to remain in the Medicare program. It will evaluate the CMHC's application and the recommendations of the SA and FI, the materials collected by the site visit contractor as a result of the site visit (the Site Visit Assessment Tool, the CMHC Site Visit Summary and the medical records), as well as the applicable sections of the Act, HCFA Regulations, PHSA, and the guidance contained in the SOM, as a part of its decision. If there are issues of provider-based, alternative sites, or operating across State lines, these should be resolved concurrently with a decision to approve or deny the CMHC for Medicare participation. At the request of the FI, at the time of Medicare enrollment, the RO will also consult with its Regional Attorney regarding State screening laws to determine their applicability to applicant CMHCs and those undergoing change of ownership. The RO will then provide to the FI verification, based on State law or other designation, as to whether the applicant CMHC or CMHC undergoing change of ownership has the legal capacity to provide screening services for admission to State mental health facilities. In addition, if the RO is determining if an existing CMHC should remain in the Medicare program, then the RO should note whether the CMHC (including any alternative sites) has moved from the community it originally was approved to serve, and terminate the provider agreements of those CMHCs that have moved to a different community where they have not been approved to operate as a CMHC. The RO should also consider the following in making its decision:

- o Whether the CMHC applicant has reasonably demonstrated to HCFA that it is providing the core PHSA services. To substantiate the provision of 24-hour emergency services, the RO may invoke unconventional measures such as calling the CMHC after hours to assess the response to, and management of, emergency calls;

The RO will not approve an entity as a CMHC unless and until the CMHC has reasonably demonstrated that it has provided the core services to a sufficient number of patients in accordance with SOM §2252 G. Additional records aside from those that were collected as part of the onsite visit that show provision of the core services by the CMHC must be sent to HCFA upon request and must be available at the site for which the CMHC is requesting Medicare approval. This includes

records for patient services provided by a CMHC under an arrangement, because the CMHC is responsible for those patients the same as if the services were provided directly by the CMHC. In cases where there is doubt about the validity of medical records submitted by a CMHC during the onsite visit to substantiate the delivery of core services, the RO may also contact the beneficiaries (or their representatives) whose medical records are in question to validate the services cited in the medical records (if necessary, contact HCFA's Office of Financial Management, Program Integrity Group, Division of Provider and Supplier Enrollment for further guidance on handling beneficiary interviews or if you require additional assistance or support in making the interviews);

- o Whether, based on information collected during the onsite visit, the CMHC applicant has reasonably demonstrated to HCFA that it has met all of the service and threshold requirements required of all new CMHCs, per SOM §2250 G;

- o Whether the facility is providing all of the core services with the exception of one which you determine it cannot provide due to preclusion under State law. Consult with your Regional Attorney before issuing a denial of the applicant's request for Medicare approval based on an issue of State law; and

- o That an entity applying as a CMHC does not have to receive block grant funds in order to meet Medicare requirements as a CMHC.

The RO should also be aware that to preserve the consistency of information being released to the public, it will serve as the contact point for inquires regarding Medicare CMHC applicants. However, as always, press inquiries should be referred to the HCFA Press Office.

G. The Role of the national CMHC Site Visit Contractor.--The national CMHC site visit contractor will work in partnership with the RO, SA and FI within the established process for CMHC enrollment to conduct onsite visits of all applicant CMHCs, CMHCs undergoing changes of ownership, and a limited number of existing CMHCs that HCFA has cause to believe are not in compliance with all State and Federal requirements. Therefore, this contractor will conduct a site visit at the request of the FI after the FI has completed its review of Form HCFA-855 and recommended that the CMHC be enrolled in the Medicare program. Once the site visit has been completed, the national site visit contractor will send all of the site visit materials to the SA so that those materials may be forwarded to the RO with all of the other accompanying enrollment paperwork. After the RO receives all of the enrollment paperwork and site visit materials, it will evaluate them, make an enrollment decision, and determine if a CMHC applicant should be approved or denied, or whether an existing agreement should be terminated. As the national CMHC site visit contractor commences its work, it will be contacting the ROs, FIs and SAs to establish contact points and determine best practices for a seamless CMHC enrollment process with the addition of the site visit requirement. Questions regarding the site visit process may be directed to the HCFA's Office of Financial Management, Program Integrity Group, Division of Provider and Supplier Enrollment.

H. Facility Alleges it is Provider-Based.--Medicare coverage of partial hospitalization services provided by a hospital to its outpatients became effective December 22, 1987, under §1861(ff) of the Act. Hospital outpatient departments do not need to qualify as CMHCs to initially provide or continue to provide partial hospitalization services. Although the statute does not preclude HCFA's approval of hospital-based CMHCs, an entity, for the purposes of providing partial hospitalization services, can qualify under Medicare either as a hospital outpatient department OR a CMHC that is hospital-based. An entity does not have the option to qualify as both a hospital outpatient department and a hospital-based CMHC to provide partial hospitalization services. Allegations of provider-based, whether alleged initially by the applying CMHC, or subsequent to HCFA approval as a CMHC, will be developed using the guidelines contained in SOM §2004.

I. Facility Requests an Alternative Site to be Approved Initially or Subsequent to Approval-- In accordance with §1913(c)(1) of the PSHA, CMHCs are required to provide mental health services principally to individuals who reside in a defined geographic area (service area). The service area means the geographic territory which includes a community that is served or proposed to be served by an existing or proposed CMHC. A service area may be delineated by factors such as population distribution, natural geographic boundaries, and transportation accessibility. Specific examples of a service area may include townships, school districts and municipalities. A CMHC must be able to serve persons in or near where the CMHC is, or is to be, situated. Therefore, CMHCs must service a distinct and definable community. If the CMHC intends to operate outside the community, it must have a separate Medicare provider agreement/number. Some CMHCs will propose to serve at an alternative site to its primary location. The RO determines the confines of the community in the event that the CMHC requests to operate such an alternative site. In making this judgement, the RO will consider the actual demonstrated transportation patterns of the CMHC clients within the community to assure that all core services and partial hospitalization services are available from each alternative site within the community. Also, the RO, with any necessary assistance from the SA, will determine if the proposed alternative site is permissible or whether the entity must seek a separate provider agreement/number for the proposed alternative site because it serves a different community. If a CMHC operates a HCFA-approved alternative site, the site is not required to provide all of the core PSHA services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC. Approvals of such alternative sites should be very limited, because CMHCs must serve a distinct and definable community, and also because HCFA has not limited the number of CMHCs an entity may submit for Medicare approval as long as these proposed CMHCs serve different communities. Each case considered for an alternative site will be based on its own merits. The following guidelines also apply when making determinations relating to alternative sites of CMHCs:

- o An applicant CMHC must identify for HCFA the site where it intends to operate the CMHC as well as any proposed alternative sites where it intends to provide partial hospitalization services. This information is specifically requested on the HCFA Form 855. The RO will inform the CMHC if it determines that the proposed alternative site must be separately approved because it is not a part of the community where the CMHC is located;

- o CMHCs are required to notify HCFA if, after approval and issuance of a provider agreement, they propose to add or delete an alternative site (SOM §3224). Reporting such a change is also a part of the HCFA enrollment process (SOM §2005 D.1);

- o The PSHA core service records, as well as the partialization hospitalization records of the primary site and any other approved alternative sites within the CMHC's community, must be available for review at the primary site; and

- o When the onsite visit is made to a CMHC subsequent to its approval, the national site visit contractor conducting the visit will request the CMHC to identify any and all alternative sites it may have operating and requesting payment through the approved provider agreement/number, and inform the RO via the completed Site Visit Assessment Tool. Assuming that the RO was aware of the alternative sites, it may re-evaluate its previous decision under these guidelines and determine if these locations may continue to be approved under the existing provider agreement or must be approved as a separate CMHC. The RO may also give this consideration to those CMHCs that failed to notify HCFA of the alternative site. In either situation, if the RO determines that these locations are not located within the CMHC's distinct and definable community, it will inform the CMHC that if it has not requested approval for the site(s) as CMHCs within 60 days of RO notification to the CMHC, the RO will request the FI to deactivate the CMHC's billing number until such time as the CMHC either ceases to provide services at the unauthorized alternative site or until the alternative site requests and receives a billing number of its own as a CMHC. If the CMHC does

not request approval of the outside-the-community operation that it has been told must have its own provider agreement/number, and does not notify HCFA of its intentions with respect to this location, the RO may terminate the CMHC's provider agreement if it determines that the CMHC is not providing services principally in the original service area for which it was approved.

J. RO Approval of CMHC Request for Medicare Approval.--If the RO approves a CMHC for Medicare participation, it assigns the CMHC a provider number from the series 1400-1499, 4600-4799 and 4900-4999 (SOM §2779), and determines the effective date of the provider agreement. The effective date of Medicare participation is the date the RO signs the provider agreement, after determining that all Medicare requirements, including enrollment, are met (SOM §2004). A CMHC that only receives Federal funds through Medicare Part B is not required to comply with various civil rights statutes enforced by the Department of Health and Human Services (DHHS), Office for Civil Rights. However, if the CMHC participates in the Medicaid Program or receives any other financial assistance such as grants from DHHS, it must comply with all applicable civil rights statutes.

The RO will notify the applicant CMHC of its decision. The notice will also address any related issues such as approval/disapproval of the CMHC as provider-based and approval/disapproval of additional offices, as appropriate. The RO will send copies of its notification to the FI and the SA.

K. RO Denial of CMHC Request for Medicare Approval.--If the RO determines that a CMHC applicant's request for Medicare must be denied, the reason will usually relate to the applicant's failure to provide the core PHSA services or the applicant's failure to meet threshold and service requirements. Use the Model Denial Letter for CMHC Applicants, Failure to Provide Core Services, if you determine that the applicant fails to provide one or more of the core PHSA services. Model Denial Letter for CMHC Applicants, State Restriction on Screening, is designed for use when an application for participation as a CMHC in the Medicare program is being denied SOLELY because the CMHC is precluded by State law or regulation from providing the core service of screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

Model Denial Letter for CMHC Applicants, Failure to Meet Threshold and Service Requirements, should be sent when the RO determines that the CMHC applicant does not meet the minimum threshold and service requirements. All model letters provide the applicant with an opportunity for a reconsideration of the decision to deny the application. If the applicant is being denied for another reason under 42 CFR Part 489.12 (a), you must develop a notice to advise the applicant CMHC of the reason for the denial. When the onsite visit is made to the CMHC, and the CMHC cannot be located, deny the application.

If the applicant CMHC requests a timely reconsideration, examine any evidence submitted by the applicant CMHC as to why it believes the initial determination was incorrect. If you determine that the denial must be affirmed, provide the CMHC with an adequate explanation of your findings of non-compliance for each of the unmet core service requirements. Specifically address any new evidence submitted via Statement of Findings and/or via Statement of Threshold and Service Requirement Findings. Offer the denied applicant an opportunity for an Administrative Law Judge (ALJ) hearing.

L. Approved Provider Changes Ownership.--CMHCs undergoing a Change of Ownership (CHOW) are treated as other providers (See SOM §§3210-3210.5, and §2005 F.) with the following exceptions:

o **Provider Agreement is Assigned, SA Role.**--The provider is required to report the CHOW to the SA. If this reporting is not done, or not done timely, the provider agreement is automatically assigned. (If the CHOW is reported to the FI or RO, the FI or RO will forward the CHOW to the SA to initiate the CHOW.) The SA will send the new owner a copy of all of the

materials under SOM §2252 C and follow the instructions in SOM §3210.5 for an assigned provider agreement. The SA, upon receipt of the requested materials (attestation, pertinent application information about the new owner, Form HCFA-855, Assigned Provider Agreement) will forward the Form HCFA-855 to the FI for verification UNLESS the SA is aware that the CMHC does not meet the core service screening requirement at §1913(c)(1) of PHSA because it is not among the entities that may conduct screening in the State; or it does not meet applicable State licensing or certification requirement for CMHCs, or the new owner has moved the CMHC to a new community without notifying HCFA. In these cases, the file will be forwarded directly to the RO for an involuntary termination of the provider agreement.

In the absence of any of the above situations that may result in a termination of the provider agreement, once the FI receives the application materials and has completed its review of those materials and finds no issue with the CHOW, the FI contacts the national site visit contractor to initiate a site visit within 6 months. After the site visit has been completed, the results will be sent to the SA. The SA will subsequently send the completed site visit package as indicated in SOM §2252 D to the RO.

o Provider Agreement is Assigned, FI Role.--The FI will verify the information on the Form HCFA-855 and inform the RO. It will, following verification of the enrollment information, request the national site visit contractor to conduct an onsite visit of the CMHC under the new ownership within 6 months. The site visit results will then be forwarded to the RO for any necessary action depending on the findings.

o Provider Agreement is Assigned, RO Role.--The RO will follow SOM §§3210-3210.5 and §2000 F in initially processing the CHOW unless the RO is aware that the screening State licensure or State certification requirements are not met by the CMHC, absent the on-site visit. If there are requirements that are not met, the RO should follow procedures to terminate the provider agreement. The RO should also ascertain if the CMHC has moved to a different community from that which it was originally approved as a CMHC. If so, the RO may terminate the assigned provider agreement because the CMHC has moved, without notification to and subsequent approval from the RO, to a different community than the one it was approved to serve. If the CMHC does not meet any of the termination criteria, after 6 months, the national site visit contractor will be conducting a site visit of the new owner, and the resulting documentation from the visit will be forwarded to the RO by the SA. (Follow procedures in SOM §2252 F for reviewing site visit materials.) If it is determined from the site visit that the new CMHC owner is not in compliance with all Federal and State requirements and/or has moved since the CHOW to a new community, consider terminating the provider agreement. In some instances the site visit documentation may not yield enough substantial evidence to justify termination of the new CMHC owner's provider agreement. However, there may be sufficient cause to investigate the matter further.

If after the site visit the RO has determined that the CMHC has not moved from its community and meets all applicable State and Federal requirements, it should indicate this determination to the FI and SA. The RO should note that if the CMHC does not report the CHOW timely, the provider agreement is automatically assigned to the new owner. Note that the effective date for all CHOWs is the date of the sale.

NOTE: If a potential purchaser of a CHOW should ask the SA, FI or RO prior to consummating a CHOW, about what will happen if he/she buys a CMHC that is not permitted to do screening in the State, or has a State licensure or certification problem with respect to licensure or certification for CMHCs, or if he/she intends to relocate the CMHC to another community, he/she should be forewarned about the possibility of termination of the provider agreement. The RO should check with the State to determine if, under the State law, provision of screening extends to the new owner.

o Approved Provider Changes Ownership, Provider Agreement is not Assigned.-- If the new owner chooses not to have the former owner's provider agreement assigned to him/her, the former owner's provider agreement will be terminated and the new owner, if he/she wants to participate in Medicare, must come into the Medicare program as a new applicant (see SOM §2252 B.). Once a site visit has been completed, the RO will terminate the CMHC seller's provider agreement effective with the date of the CMHC sale. In addition, the RO should note that in checking the new CMHC owner's compliance with the threshold and service requirements, the date of the sale is the first day of the new owner's first business quarter. If all Federal and State requirements are met, the RO will issue a new provider agreement to the new CMHC owner. If the CMHC does not meet all necessary requirements, the RO will issue a notice of that determination to the FI and SA. Note that the effective date of all CHOWs is the date of sale.

M. Voluntary Termination.--A Medicare participating CMHC may voluntarily terminate its provider agreement at any time. The RO will follow the guidance in SOM §§3046, 3047, and 3048 in processing the termination. Also, if you are unable to locate the CMHC at the site approved for entry into the Medicare program, and you have exhausted all reasonable attempts to locate the CMHC, including a contact with the FI to ascertain if the CMHC has been billing Medicare, you should process an involuntary termination. (See Model Letter for CMHC that has Ceased Operating, Exhibit 281.)

N. Involuntary Termination.--An involuntary termination of a CMHC's provider agreement will usually be based on an onsite visit in which it is discovered that the participating CMHC is not providing one or more of the core services. The onsite visit may have resulted from a complaint, a periodic revalidation of the provider or because the CMHC met the most egregious criteria discussed in SOM §2252 O. Following a review of the site visit findings and any other relevant information, if the RO determines that a termination is in order, it will use the Model Letters, Notice of Termination of Provider Agreement, Exhibit 280, and Notice of Findings of Non-Compliance, Exhibit 279 in notifying the CMHC of the termination. If the CMHC provides additional documentation of having provided the core services subsequent to the notification of Findings of Non-Compliance, work closely with your Regional Attorney in making a determination of whether to continue with the termination. If the CMHC moves from the approved site issued by the Provider Agreement/Number to a different community, this should be treated as an involuntary termination (see SOM §2252 M).

O. Identifying the "Most Egregious" CMHCs for Termination Action.-- Since there are no Conditions for Participation for CMHCs, many participating CMHCs have never had an onsite visit and are in the Medicare program solely because their attestation of compliance with the Federal requirements has never been challenged. HCFA has developed criteria as a way of identifying CMHCs that may be among the worst program offenders in terms of not meeting Federal requirements for CMHCs. The criteria are as follows:

o History of Inappropriate Billing Data.--Inappropriate billing is any one of the following circumstances:

- Unusual pattern of billed charges per patient per CMHC which significantly deviates from the State or national CMHC payments per patient (as determined by RO review of HCIS data for a recent 6-month period);

- Denial of 50 percent or more of services reviewed (after focused medical review by the FI (e.g., 15 percent of total charges submitted));

- Overpayment in excess of 15 percent of the CMHC's total Medicare payments (identified by FI);

- CMHC's cost report shows no other services rendered other than services reimbursed by Medicare or no charges/services paid for by personnel needed to render all of the required core services. (RO or FI to refer to Worksheet S, Part II, lines 14 through 23 and worksheet C, lines 29-38.)

NOTE: When a cost report shows Medicare as the sole source of income, the RO should request documentation from the CMHC to determine if core services are being provided. If documentation is not provided or is inadequate, termination of the Provider Agreement should be considered and recommended for review by the Regional Attorney.

o Failure of CMHC to provide two or more of the core services described in §1913(c)(1) of the PHSA as determined by:

- RO review of onsite inspection findings; or

- RO review of documentation voluntarily provided from any source, including a CMHC, SA , or FI, or any documentation requested for review by the RO.

o The RO Review of Any Relevant Documentation or Information--The RO should review the CMHC's inappropriate billing data obtained from the FI that indicates that the CMHC may not meet the Federal requirements in the Act, including those provisions that are cross-referred to the PHSA. If an onsite visit is necessary, the RO, considering the recommendation of the national site visit contractor, will determine whether the CMHC meets the requirements in §1861(ff) of the Act with specific attention given to the PHSA core service provisions and other regulatory requirements such as whether physicians' orders and plans of care exist for the Medicare partial hospitalization billings.

A final determination that a CMHC meets the "most egregious" criteria will be based on a full review of all relevant facts, and not solely on issues related to inappropriate billing or failure to provide one of the core services.

o Deactivation of the CMHC's Medicare Provider Billing Number--The FI will periodically review CMHC billing records. If the FI observes that for the past 12 months the CMHC has not submitted any claims for partial hospitalization services, it may deactivate the CMHC's billing number rendering the CMHC an inactive Medicare provider. Deactivation is neither a termination of the provider agreement nor a suspension of Medicare payment. It simply means the Medicare provider agreement remains in effect, but the FI will make no further payments to the CMHC until it receives from the CMHC an updated Form HCFA-855 which it must verify. The FI will use the Medicare Provider Billing Number Deactivation Letter, Exhibit 277 when notifying the CMHC of the deactivation. Since this is not a termination, if the CMHC is using its Medicare approval in order to receive Medicaid benefits, it could continue to receive Medicaid. If the FI subsequently learns that the CMHC wants its provider agreement terminated, it will inform the RO.

LIST OF EXHIBITS (Cont.)

- 245 CLIA Adverse Action Extract, HCFA-462A/B Reserved
- 246 Model Letter: Regional Office Notifying a State-Operated Laboratory of Cited Deficiencies and Requesting a Plan of Correction
- 247 Notice of (Limitation or) Revocation of a Laboratory's CLIA Certificate - No Immediate Jeopardy
- 248 Notice of Proposed Limitation, Suspension, or Revocation of the CLIA Certificate; Opportunity for a Hearing - No Immediate Jeopardy
- 249 Model Letter: Send to the Laboratory in Conjunction With the Notice of Sanction, In Order to Officially Inform the Laboratory that the Responsibility Lies With the Laboratory to Achieve Compliance, Even if They Have Successfully Completed the Directed Plan of Correction
- 250 Notice of the Reissuance of a CLIA Certificate In Order to Keep a Laboratory Operational if it is Due to Expire Prior to the Administrative Hearing
- 251 Model Letter: Offering the Opportunity for a Reconsideration of the Addition of Specialties or Subspecialties by a Laboratory is Denied by HCFA
- 252 Model Letter: To Laboratory Director to Accompany the AQAS Instrument
- 253 Reserved for SAQIP
- 254 Model Letter: Notification to Applicant that Medicare General Enrollment Health Care Provider/Supplier Application Has Been Denied
- 255A Model Letter: Notification of Pending Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
- 255B Model Letter - Notification of Involuntary Termination Based on CHOW Review of the Medicare General Enrollment Health Care Provider/Supplier Application
- 256 Form HCFA-855 - Medicare and Other Federal Health Care Program General Enrollment Health Care Provider/Supplier Application
- 257 Form HCFA-855C - Medicare and Other Federal Health Care Program Change of Information Health Care Provider/Supplier Application
- 258 Form HCFA-855R - Medicare and Other Federal Health Care Program Individual Reassignment of Benefits Health Care Provider/Supplier Application
- 259 Minimum Data Set Automation Contract/Agreement Approval RO Checklist
- 260 MDS 2.0 Discharge and Reentry Flowchart
- 261 Privacy Act Statement - Health Care Records
- 262 Correction Policy Flowchart
- 263 Submission Timeframe for MDS Records
- 264 HCFA-672 - Resident Census and Conditions of Residents

LIST OF EXHIBITS (Cont.)

- 265 HCFA-802 - Roster/Sample Matrix
- 266 HCFA-802P - Roster/Sample Matrix Provider Instructions (use with Form HCFA-802)
- 267 HCFA-802S - Roster/Sample Matrix Instructions for Surveyors (Use with Form HCFA-802)
- 268 Facility Characteristics
- 269 Facility Quality Indicator Profile
- 270 Resident Level Summary
- 271 Quality Indicator Matrix
- 272 Overview of MDS Submission Record
- 273 Correction Policy Summary Matrix
- 274 Definition of Selected Dates in the RAI Process
- 275 Attestation Statement for CMHCs
- 276 Health Insurance Benefit Agreement for CMHCs
- 277 Fiscal Intermediary (FI) Provider Billing Number Deactivation Letter Used by FI
- 278 Model Denial Letter for CMHC Applicants—State Restrictions on Screening
- 279 Model Letter – Notice of Findings for Non-Compliance for CMHCs
- 280 Model Letter – Notice of Termination of Provider Agreement for CMHCs
- 281 Model Letter – CMHC That Has Ceased Operating
- 282 Model Letter – Participation in Medicare as a CMHC Providing Partial Hospitalization Services (Including Threshold and Service Requirements)
- 283 Model Letter – Notice of Failure to Meet Threshold and Service Requirements, CMHCs

Exhibit 275

ATTESTATION STATEMENT

Complete the following attestation statement and return it with your letter requesting participation in the Medicare program as a Community Mental Health Center providing partial hospitalization services.

The _____ (name of facility) hereinafter referred to as the Community Mental Health Center (CMHC), hereby agrees to:

(A) Maintain compliance with §1861(ff)(3)(B)(i) of the Social Security Act (the Act) by providing the services described in §1913(c)(1) of the Public Health Service Act (PHSA) (which supersedes the former §1916(c)(4) of the PHSA);

(B) Maintain compliance with §1861(ff)(3)(B)(ii) of the Act by meeting applicable licensing or certification requirements for CMHCs in the State in which it is located; and

(C) Maintain compliance with the requirements set forth in Parts 400, 410, 424, and 489 of Chapter IV, Title 42 of the Code of Federal Regulations, and to report promptly to the Health Care Financing Administration any failure to do so.

I certify that I have reviewed each Federal requirement indicated above and that _____ (name of facility) is in compliance with the applicable requirements. I also certify that I agree to comply with the provisions of §1866 of the Act and Medicare regulations applicable to CMHCs.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years or both. (18 U.S.C. §1001).

Name _____ Title _____

Date _____

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0770. The time required to complete this information collection is estimated to average four (4) hours per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26, and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Exhibit 276

HEALTH INSURANCE BENEFIT AGREEMENT
(AGREEMENT WITH PROVIDER PURSUANT TO SECTION 1866 OF THE SOCIAL SECURITY ACT, AS AMENDED AND TITLE 42 CODE OF FEDERAL REGULATIONS (CFR) CHAPTER IV, PART 489)

AGREEMENT
BETWEEN
THE SECRETARY OF HEALTH AND HUMAN SERVICES
AND

_____ doing business as (DBA) _____
In order to receive payment under Title XVIII of the Social Security Act, _____

D/B/A _____ as the provider of services, agrees to conform to the provisions of Section 1866 of the Social Security Act and applicable provisions in 42 CFR.

This agreement, upon submission by the provider of services of acceptable assurance of compliance with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 as amended, and upon acceptance by the Secretary of Health and Human Services, shall be binding on the provider of services and the Secretary.

In the event of a transfer of ownership, this agreement is automatically assigned to the new owner subject to the conditions specified in this agreement and 42 CFR 489, to include existing plans of correction and the duration of this agreement, if the agreement is time limited.

ATTENTION: Read the following provision of Federal law carefully before signing.

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years or both (18 U.S.C. Section 1001).

Name _____ Title _____

Date _____

ACCEPTED FOR THE PROVIDER OF SERVICES BY:

NAME (SIGNATURE) _____

TITLE _____

DATE _____

ACCEPTED BY THE SECRETARY OF HEALTH AND HUMAN SERVICES BY:

NAME (SIGNATURE) _____

TITLE _____

DATE _____

ACCEPTED FOR THE SUCCESSOR PROVIDER OF SERVICES BY:

NAME (SIGNATURE) _____

TITLE _____

DATE _____

Exhibit 276 (Cont.)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0770. The time required to complete this information collection is estimated to average fifteen minutes per response, including the time to review instructions, searching existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26 and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Exhibit 277

FISCAL INTERMEDIARY (FI) MEDICARE PROVIDER BILLING NUMBER
DEACTIVATION LETTER USED BY FI

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

The FI, acting on behalf of the Health Care Financing Administration (HCFA) to process and pay your Medicare claims, has observed that in the past 12 months no claims have been submitted under your Community Mental Health Center (CMHC) Medicare billing number, (insert billing number). Due to lack of activity, HCFA will deactivate your billing number, as of (add date of deactivation), rendering your CMHC an inactive Medicare provider. Deactivation occurs when a CMHC's provider agreement remains in effect, but the FI has suspended payment to the CMHC until the FI has received and verified the CMHC's updated Form HCFA-855 information.

You may wish to resume your CMHC's status as an active Medicare CMHC provider. However, to ensure that current data is on file, it will be necessary for you to complete an enrollment application, Form HCFA-855 if you have never done so, or completely update your current Form HCFA-855 when the CMHC resumes service to Medicare beneficiaries and bills for services rendered on their behalf. Any claims incurred before the reactivation of the CMHC billing number can be paid by the FI retroactively within the standard time limits for filing claims as specified in 42 CFR Part 424.44. You may obtain the Form HCFA-855 from your FI, State Licensing, and/or Survey and Certification Agency.

You may elect to submit a letter to the FI (insert fiscal intermediary address), State Licensing or Survey and Certification Agency (insert SA address) requesting a voluntary termination of your Medicare provider agreement, if you will no longer bill Medicare.

If you have any questions regarding this letter, please contact (insert name and phone number of FI contract).

cc:
HCFA Regional Office

FI Provider Enrollment Manager

Exhibit 278

MODEL DENIAL LETTER FOR CMHC APPLICANTS--
STATE RESTRICTIONS ON SCREENING

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

This is to inform you of the Health Care Financing Administration's initial determination (see 42 CFR Part 498.3) that your facility does not meet the requirements for certification to participate in the Medicare program as a community mental health center (CMHC) providing partial hospitalization services.

In order to be certified as a CMHC providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff)(3) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1) of the Public Health Service (PHS) Act) and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24 hour-a-day emergency care services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

After a careful review, HCFA has determined that you do not meet the statutory requirements for a CMHC. This is because, as discussed in the attached statement of findings, you do not provide screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission, one of the services listed in §1913(c)(1) of the PHS Act, and required by §1861(ff)(3)(B) of the Social Security Act. Our review indicates that pertinent requirements (see attachment) for the State of [insert name of State] place restrictions on who may perform screening, and specifically preclude your facility from providing this service.

If you believe that this initial determination is not correct, you may request that it be reconsidered. The request must be submitted in writing to [insert name and address] within 60 days of the date you receive this notice in accordance with 42 CFR Part 498.22. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later. The request should state the legal and factual reasons why you consider the decision to be incorrect and should include any documentation supporting these legal and factual conclusions.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 279

MODEL LETTER
NOTICE OF FINDINGS OF NON-COMPLIANCE

XYZ Community Mental Health Center
Address:

Dear Sir or Madam:

After careful review of the facts, the Health Care Financing Administration (HCFA) has determined that [insert name of provider] fails substantially to meet the applicable provisions of §1861(ff)(3) of the Social Security Act (the Act) and regulations and/or fails to comply substantially with the provisions of its Health Insurance Benefit Agreement (provider agreement). In accordance with §1866 of the Act and 42 CFR Part 489.53, HCFA may terminate a Community Mental Health Center's (CMHC) provider agreement to participate in the Medicare program when it determines that a CMHC is not complying with the provisions of the Act, applicable regulations, or the provider agreement.

[Insert provider name] entered into a provider agreement as a CMHC on [insert date]. In that agreement, [insert provider name] agreed to: (A) Maintain compliance with §1861(ff)(3)(B)(i) of the Act by providing the services described in §1913(c)(1) of the Public Health Service Act (PHSA); (B) Maintain compliance with §1861(ff)(3)(B) of the Act by meeting applicable licensing or certification requirements for CMHCs in the State in which it is located; and (C) Maintain compliance with the requirements set forth in Parts 400, 410, 424 and 489 of the Chapter IV, Title 42 of the CFR, and to report promptly to HCFA any failure to do so.

To participate as a provider of partial hospitalization services in the Medicare program an entity must meet the statutory requirements for a CMHC. These requirements are found at §1913(c)(1) (formerly §1916(c)(4) of the PHSA). The core PHSA services that an entity must provide in order to be approved as a CMHC are as follows: Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24 hour-a-day emergency care services; day treatment or other partial hospitalization services, or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission. A CMHC is also defined at 42 CFR Part 410.2. In accordance with the PHSA, the core services must actually be provided by a CMHC and not just be available to be provided. The core services must continue to be provided following Medicare approval.

Please see attached findings of noncompliance (Attachment 1). You have 15 calendar days from the date of receipt of this notification to respond to the attached findings. Please include any documentation you have which supports any factual assertions you make, as well as any legal conclusions with which you disagree.

This documentation should include any material that you consider relevant, for example, medical records, logs, and contractual documentation. While there is no maximum number of clinical records or materials that you may submit, we believe that 5 clinical records for each core service (a maximum of 25 patients) should generally suffice for purposes of this review.

If you demonstrate that [insert provider name] provides the requisite core services, no termination will be effected. However, if after review of the information as well as the review of the team's findings and documentation, HCFA still believes that you do not provide one or more of the required services, it will provide 15 calendar days notice of its decision to terminate [insert provider name] prior to termination.

Exhibit 279 (Cont.)

Page 2

Please send the response in writing to:

(*Insert the following sentence as applicable. We have determined that the State of _____ precludes your facility from providing (list the core service(s)).

Sincerely,

Associate Regional Administrator
(or its equivalent)

Attachment

Exhibit 279 (Cont.)

ATTACHMENT 1

STATEMENT OF FINDINGS

Provide the CMHC with an adequate explanation of HCFA's findings of non-compliance for each of the unmet core service requirements. For example:

You previously attested over a penalty clause that you were providing all of the PHSA core services. However, an onsite visit was made to your facility on 00/00/00, and you were asked to provide any and all documentation to substantiate the provision of each of the core services. In order to demonstrate the provision of outpatient services for the elderly, you provided a patient record for JOHN DOE. Our review of this record determined that Mr. DOE was 14 years old. Therefore, this record did not substantiate the provision of outpatient services for the elderly. No other record or documentation was submitted for this core service. Therefore, we have concluded that you have failed to provide outpatient services for the elderly, one of the core services listed in §1913(c)(1) of the PHSA and required by §1861(ff)(3)(B) of the Social Security Act.

MODEL LETTER

NOTICE OF TERMINATION OF PROVIDER AGREEMENT

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

On [insert date], we notified you of our findings that the [insert provider name] Community Mental Health Center (CMHC) failed to provide the following core Public Health Service Act (PHSA) services as mandated by §1913(c)(1) of the PHSA and required by §1861(ff)(3) of the Social Security Act (the Act) to qualify as a CMHC for Medicare purposes. We informed you that if you had additional evidence to show that you provided the core services that you had 15 calendar days to respond to our findings.

(The RO should choose one of the following statements:)

— The 15 calendar day period has expired and you failed to submit evidence of having provided the following core services; or

— On [insert date], you provided additional information in the form of [insert listing of materials submitted]. We have reviewed this documentation. It [does/does not] change our earlier decision that you failed to provide the core PHSA services.

(If the RO has determined that the additional material submitted by the CMHC changes the earlier decision of unmet PHSA core service requirements, the notification is complete.)

(If the CMHC presented additional materials as evidence of its compliance with the PHSA core requirements, and the RO has determined that this material does not change its earlier decision concerning the unmet core requirements, note the evidence submitted and respond to the information and documents; or lack thereof with respect to the core services you found the provider did not meet with a detailed explanation of why it has not changed the determination and insert the following paragraphs:)

As we informed you earlier, in accordance with §1866 of the Social Security Act and 42 CFR Part 489.53, HCFA may terminate a CMHC's provider agreement to participate in the Medicare program when it determines that a CMHC is not complying with the provisions of the Act, applicable regulations, or the provider agreement.

Based on our determination that [insert provider name] does not provide [insert list of core services not furnished] of the four core services, we conclude that it has failed substantially to comply with the provisions of its provider agreement, or to meet the provisions of §1861(ff)(3), which require it to provide all four of these services, and therefore, its provider agreement must be terminated in accordance with §1866 of the Act, and 42 CFR Part 489.53. The date on which the Medicare provider agreement terminates is [insert date].

We will publish a legal notice in the newspaper 15 calendar days prior to termination. You will be advised of publication of the notice.

Exhibit 280 (Cont.)

Page 2

If you believe this decision is not correct, in accordance with 42 CFR Part 498.5(a)(2), you must file a request with HCFA within 60 days from receipt of this notice for a hearing before an Administrative Law Judge. The request must state the issues, or the specific findings of fact with which you disagree, and the specific reasons for the disagreement. Your request for a hearing should be sent to:

If you have any additional questions concerning this determination, please direct your inquiry to:

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 281

MODEL LETTER

COMMUNITY MENTAL HEALTH CENTER (CMHC) THAT HAS CEASED OPERATING

Provider Number: _____

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

This is to notify you that we determined that [insert name and address of provider] has closed on [insert actual date of closing, or if unknown, date established by the RO]. Under the provisions of 42 CFR Part 489.52(b)(3), your provider agreement with the Secretary of Health and Human Services will be terminated [insert date]. No payment can be made under the Medicare program for services on or after that date.

This determination is based on the following: On [insert date], this office sent you a notice concerning [insert purpose of notice]. The notice which was sent to your facility's last address of record was subsequently returned to this office by the U.S. Postal Service as undeliverable. We then contacted [list the names of all other entities that were contacted; e.g., State survey agencies, State mental health associations, etc., and the date they were contacted] in an effort to locate your facility. Those attempts were unsuccessful. We also contacted [name of servicing intermediary] and were informed that your facility stopped billing [or has never submitted bills, if applicable] Medicare on [insert last day of billing].

The [insert name and address of provider] will no longer participate in the Medicare program (Title XVIII of the Social Security Act) effective [insert date]. The agreement between [insert name of provider] and the Secretary of Health and Human Services will be terminated on [insert date of termination] in accordance with the Social Security Act.

If you disagree with this notice, you must respond in writing to this office within 15 days of the date of this notice. We will publish a public notice of your facility's termination in the [insert name of local newspaper].

If your facility is reopened and you again wish to participate as a CMHC provider, you should contact [insert name of State survey agency]. They will assist you in taking the actions necessary to become certified for participation as a provider. Please let me know if you have any questions concerning this action.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 282

MODEL LETTER

PARTICIPATION IN MEDICARE AS A
COMMUNITY MENTAL HEALTH CENTER
PROVIDING PARTIAL HOSPITALIZATION SERVICES
(INCLUDING THRESHOLD AND SERVICE REQUIREMENTS)

XYZ Community Mental Health Center
Address

Dear:

In order to be certified as a CMHC for the purpose of providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1)) of the Public Health Service (PHS) Act) and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24-hour-a-day emergency care services; day treatment or other partial hospitalization services; or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

The statute requests that an applicant CMHC be providing the core services at the time of certification, not at some future point in time. Accordingly, HCFA will look for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

- o Is fully operational for a sufficient period of time that enables us to be reasonably assured of the facility's compliance with program requirements. We believe one business quarter would provide us with the information we need to assess compliance;
- o Has served, as evidenced by complete, onsite medical record documentation from within 3 months of the date of the initial Medicare application for new applicants or the date of sale for a change of ownership, a sufficient number of persons to enable us to be reasonably assured that the facility is, in fact, complying with basic program requirements. We believe, that to achieve this objective, a facility should have served at least 10 non-Medicare patients, including:
 - A minimum of three patients for which medical records demonstrate that the CMHC has:
 - + The legal capacity under State law to provide screening services for admission to State mental health facilities;
 - + The capability and clinical expertise to provide such screening services; and

- + Provided screening services the specific purpose (e.g. reason for referral) of which is to assess the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement.
- A minimum of 3-day treatment or partial hospitalization or psychosocial rehabilitation patients (this is group treatment and three patients is the smallest number the CMHC could justify as a group); and
- At least one patient from each of the four outpatient categories:
 - + Children;
 - + Elderly;
 - + Chronically mentally ill; and
 - + Residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility.

At this time, there are no **prior service requirements** regarding the following core service:

24 hour a day emergency care services.

However, please be aware that your CMHC must be able to demonstrate that it can provide 24-hour emergency care services.

NOTE: If you are approved for Medicare participation, you are expected to continue to provide the non-Medicare services. Providing these services is ongoing and not a one-time qualifying event for Medicare participation.

The address shown in your provider agreement is where HCFA requires records of services, provided either directly or under an arrangement, be available, because the CMHC is responsible for all services.

A CMHC may provide one or more core services under arrangement with another individual, group, or entity only when the following criteria are met:

- o Service Authorized by State Law--In no case may a CMHC provide a service under arrangement when the CMHC has not been given authority to provide the service itself directly under State statute, licensure, certification, or regulation.
- o Full Legal Responsibility--A CMHC that provides a core service under arrangement with another entity remains the legally responsible authority through which comprehensive mental health services are provided. It is not sufficient for the arrangement to be a referral process where the CMHC does not assume overall management responsibility for the provision of core services by a separate individual, group, or entity. The CMHC must retain complete accountability for the services provided under the arrangement. The CMHC must retain legal, professional, and administrative responsibility to coordinate care, supervise and evaluate the services, and ensure the delivery of high quality mental health treatment.

- o Written Agreement--If a CMHC provides services under arrangement, there must be a written agreement or contract between the two parties that specifies the services to be rendered and the manner in which the CMHC exercises its professional and administrative responsibility. Furthermore, for the agreement to serve as the vehicle through which the CMHC meets the requirement to provide one or more of the core services, the terms of the agreement must be adhered to in practice. In order to verify the nature of the relationship between the CMHC and the other party, the agreement must be accessible to HCFA or its agents, and the documentation for all services rendered under arrangement must be maintained by the CMHC at the site identified in the provider agreement.

We will also assign each CMHC a provider identification number .

Those facilities that are denied approval to participate in the Medicare program will be notified and given the reason(s) for the denial.

You are required to notify the HCFA RO at the time you are planning a transfer, deletion, addition, or relocation of a service area. If operation of the entire facility is later transferred to another owner, ownership group, or to a lessee, the CMHC identification number will be automatically assigned to the successor, following notification.

Each proposed CMHC must enroll with Medicare by completing a Form HCFA-855 and independently meet the Federal requirements for CMHCs, sign a separate CMHC provider agreement and receive a separate identification number. The facility must also conform to the provisions of §1866 of the Social Security Act and all Medicare regulations applicable to CMHCs.

In addition, your application must contain at least the following:

- o The name and address of the facility;
- o The name of the responsible agent, including the address and telephone number;
- o The facility's Medicare provider number, if the facility is already participating in the Medicare program as another type of provider;
- o The Medicare provider number of the entity, if the facility is operated as part of and under control of another entity that is participating in the Medicare program;
- o The identification of the community your CMHC intends to serve, because in accordance with §1913(c)(1), CMHCs are required to provide mental health services to individuals who reside in a distinct and definable community. If a CMHC intends to operate an alternative site outside its community, the site must have a separate provider agreement/number because this would be a different community. HCFA must approve all alternative sites. If a CMHC operates a HCFA-approved alternative site, the site is not required to provide all of the core PHSA services. However, a patient must be able to access and receive the services he/she needs at the approved primary site, or at an alternative site that is within the distinct and definable community served by the CMHC;
- o The type of ownership or control (i.e, nonprofit, government);
- o The services provided with the number of full-time equivalent employees; and

Exhibit 282 (Cont.)

Page 4

- o A signed Attestation Statement indicating that the facility complies with all of the Federal requirements in §1861(ff)(3)(B) of the Social Security Act.

Sincerely,

Associate Regional Administrator
(or its equivalent)

Exhibit 283

MODEL LETTER

Notice of Failure to Meet Threshold and Service Requirements

XYZ Community Mental Health Center
Address

Dear Sir or Madam:

This is to inform you of the Health Care Financing Administration's initial determination (see 42 CFR Part 498.3) that your facility does not meet the requirements to participate in the Medicare program as a community mental health center (CMHC) providing partial hospitalization services.

In order to be certified as a CMHC providing partial hospitalization services in the Medicare program, an entity must meet the statutory requirements for a CMHC. These requirements are found at §1861(ff) of the Social Security Act, which requires that a CMHC provide the services described in §1916(c)(4) (now found at §1913(c)(1) of the Public Health Service (PHS)) Act and meet applicable licensing or certification requirements for a CMHC in the State in which it is located.

The services listed in the PHS Act that an entity must provide in order to be approved as a CMHC are as follows: outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of service areas of the centers who have been discharged from inpatient treatment at a mental health facility; 24-hour-a-day emergency care services; day treatment or other partial hospitalization services; or psychosocial rehabilitation services; and screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

The statute requires that an applicant CMHC be providing the services listed in the PHSA at the time of certification, not at some future point in time. Accordingly, HCFA looks for evidence that the applicant is already providing the core services as a pre-condition for certification. For example, HCFA will look to see that the applicant:

- o Is fully operational for a sufficient period of time that enables us to be reasonably assured of the facility's compliance with program requirements. We believe one business quarter would provide us with the information we need to assess compliance.
- o Has served, as evidenced by complete, onsite medical record documentation from within three months of the date of the initial Medicare application for new applicants or date of sale for changes of ownership, a sufficient number of persons to enable us to reasonably assure that the facility is, in fact, complying with basic program requirements. We believe that to achieve this objective, a facility should have served at least 10 non-Medicare patients, including:
 - A minimum of three patients for which medical records demonstrate that the CMHC has:
 - + The legal capacity under State law to provide screening services for admission to State mental health facilities;
 - + The capability and clinical expertise to provide such screening services; and

- + Provided screening services for which the specific purpose (e.g., reason for referral) is to assess the patient's need for admission to a State mental health facility. Where there are State requirements for the completion of required forms, court documents, or any other required documentation in response to the screening request, these documents would be evidence of providing the service. Otherwise, evidence in the screening assessment must include a clinical decision regarding the appropriate level of care and follow-up placement.
- A minimum of 3-day treatment or other partial hospitalization or psychosocial rehabilitation patients (this is a group treatment and three patients is the smallest number the CMHC could justify as a group); and
- At least one patient from each of the four outpatient categories:
 - + Children;
 - + Elderly;
 - + Chronically Mentally Ill; and
 - + Residents of its mental health service area who have been discharged from inpatient treatment as a mental health facility.

We based our decision on the fact that your HCFA Medicare Enrollment Application, Form HCFA-855 and an on-site visit completed on (insert date) by the (insert name of site visit contractor) revealed that your facility did not meet these Federal requirement(s) for CMHCs. The unmet requirement(s) was/were:

(Provide the CMHC with an adequate explanation of HCFA's findings of noncompliance for each of the unmet threshold and service requirements.) For example:

HCFA has determined that all CMHCs seeking to participate in the Medicare program must meet minimum non-Medicare service requirements before enrollment into the Medicare program. As a result of the information you provided on the HCFA Medicare Enrollment Form HCFA-855 and/or at the time of the on-site visit to your facility, it was determined that your facility does not meet the requirements at §1913(c)(1) which we refer to as threshold and service requirements. You were then provided an opportunity to substantiate your ability to meet these requirements, but you failed to do so.

If you believe that this initial determination is not correct, you may request that it be reconsidered. The request must be submitted in writing to (insert name and address) within 60 days of the date you receive this notice in accordance with 42 CFR Part 498.22. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later. The request should state the legal and factual reasons why you consider the decision to be incorrect and should include any documentation supporting these legal and factual conclusions.

If you have any questions, please feel free to contact (insert name of staff) at (insert phone number).

Sincerely,

Associate Regional Administrator
(or equivalent)

