DATE: November 5, 2007

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Initial Surveys for New Medicare Providers

Memorandum Summary

• The Centers for Medicare & Medicaid Services (CMS), together with States, seek to maintain effective quality assurance in the Medicare program at the same time that:
  – Many new providers are applying to participate in Medicare for the first time;
  – Resources are highly constrained since the President’s proposed budget for Survey & Certification (S&C) has not been fully funded for the past three consecutive years;
• Appendix A therefore contains revised survey priorities and procedures to ensure that we obtain greater value from each survey dollar expended, and that CMS’ priority structure for survey and certification activities are followed faithfully (see Appendix A);
• CMS longstanding policy makes complaint investigations, recertifications, and other core work for existing Medicare providers a higher priority compared with certification of new Medicare providers. We retain and affirm the advisability of those priorities;
• Providers that have the option of attaining accreditation that conveys deemed Medicare status conducted by a CMS-approved accreditation organization (in lieu of Medicare surveys by CMS or States) are advised that such deemed accreditation is likely to be the fastest route to certification;
• While accreditation by an accreditation organization does not suffice to demonstrate compliance with the special requirements for certain hospitals (such as rehabilitation or psychiatric hospitals or IPPS-excluded units) that receive payment outside of the Inpatient Prospective Payment System (IPPS), proper attestation of compliance with IPPS-exclusion requirements (combined with the accreditation) will permit the State and CMS to act expeditiously on the hospital’s application.

Background

The Social Security Act (the Act) provides for a system of quality assurance in the Medicare program based on objective, onsite, outcome-based surveys by federal and State surveyors. The survey and certification (S&C) system provides beneficiaries with assurance that basic standards of quality are being met by health care providers or, if not met, that remedies are promptly implemented.
CMS accomplishes these vital quality assurance functions under specific direction from the Act and in concert with States, CMS-approved accreditation organizations (AOs), and various contracts with qualified organizations. All CMS or State certification surveys for Medicare must be performed by Medicare-qualified surveyors consistently applying federal regulations, protocols, and guidance. Most types of providers or suppliers seeking to participate in Medicare must first demonstrate compliance with quality of care and safety requirements through an on-site survey.

Initial surveys of new providers or suppliers have become more challenging for four reasons:

**Resource Limitations:** For the past three consecutive years the final federal budget for Medicare survey and certification has been considerably less than the level requested by the President. The FY 2007 appropriation, for example, was $25 million less than the President’s budget request (and lower than FY 2005 levels). Although we remain hopeful that the FY 2008 appropriation will fully fund the President’s request, it may be well into the fiscal year before Congress enacts the final FY 2008 budget.

**Many New Providers:** Many additional providers have been seeking to participate in the Medicare program. Since 2002, for example, the number of Medicare-participating rural health clinics has increased by 48.7%, ambulatory surgical centers by 38.4%, hospices by 37.4%, home health agencies by 31.9%, dialysis facilities by 18.2%, and non-accredited hospitals by 9.5%. The graph to the right portrays the growth between 2002 and 2007 in the number of different providers and suppliers that constitute the main survey and certification workload.

**More Responsibilities:** Additional survey responsibilities, such as new responsibility for surveys of hospital transplant programs beginning in late 2007, have further stretched survey resources and have increased the need to pay careful attention to survey priorities.

**Anti-fraud Initiatives:** Growth in the number of certain provider types, particularly home health, has been accompanied by evidence of higher levels of fraudulent activity by a minority of such providers. The Secretary’s recent anti-fraud initiatives have called upon survey and certification to conduct additional surveys in certain areas where change of ownership indicates the need for closer review.

**CMS Priorities**

Longstanding CMS policy makes complaint investigations, recertifications, and core infrastructure work for existing Medicare providers a higher priority compared with certification of new Medicare providers. CMS directs States to prioritize federal survey functions in four priority “Tiers.” Tier 1 consists of statutory mandates, such as surveys of existing nursing homes and home health agencies. Tier 4 consists of other important work, but work that is considered
reasonable to accomplish only if higher priority functions can be accomplished within the federal budget limitations.

Many provider or supplier types (such as hospitals, ambulatory surgery centers, hospices, and home health agencies), have the option of becoming Medicare-certified on the basis of accreditation by a CMS-approved AO instead of a survey by CMS or States. In such cases, the applicants have an alternate route to Medicare certification via CMS’ acceptance of the AO’s accreditation. While the applicant will pay a fee to the AO for the initial survey, applicants may conclude that the benefits outweigh the expense, particularly the expense of time waiting for a no-cost CMS survey. Similarly, clinical laboratory surveys are not subject to the CMS prioritization structure because the laboratories pay a fee to CMS for the laboratory certification work. For all initial Medicare surveys conducted by CMS or States, there is no cost to the applicant, but the resource limitations described here require that we adhere to a clear sense of priorities in conducting our work.

Most initial surveys for providers or suppliers seeking to participate in Medicare for the first time are prioritized in a lower priority (Tier 4) for CMS and State survey agency (SA) work compared to complaint investigations and recertification of existing providers or suppliers. The increasing severity of S&C resource limitations means that the effect of this longstanding CMS priority on providers and suppliers is more pronounced now than it has been in the past. The situation is different for each State, since some States have seen a large number of new providers seeking Medicare participation while other States have not seen such an increase.

Different providers/suppliers may also experience unique options and circumstances, so that a common policy may have a different impact on different providers. We are therefore refining the CMS policy for initial surveys in order to recognize the different situations being experienced by different providers and suppliers. The revised policy in Appendix A accomplishes a number of objectives:

• **Process for Exceptions**: The revised policy explains the process by which providers or suppliers in certain unique circumstances may request from CMS an exception in their priority assignment.

• **Higher Priority for Some Unique Situations**: The “Tier 3” priority is expanded to raise the priority level for providers or suppliers in certain unusual circumstances without needing to request any special exception.

• **Tier 4 Options**: The revised policy offers a better explanation of the options available to providers whose application for new participation in Medicare represents a Tier 4 priority for survey and certification. These changes are particularly relevant to hospitals that offer services that are excluded from the Inpatient Prospective Payment System (IPPS). They provide methods by which proper attestation of compliance with IPPS-exclusion requirements (combined with the accreditation) will permit the State and CMS to act expeditiously on the hospital’s application.
In the future, CMS will explore additional actions that may strengthen oversight of hospital rehabilitation and psychiatric services, including:

(a) Revising the Medicare hospital Conditions of Participation to include the special requirements for rehabilitation and psychiatric services that are now addressed only in the IPPS-exclusion requirements at 42 CFR 412, and

(b) Conducting onsite surveys for a sample of hospitals that provide rehabilitation or psychiatric services, based on an analysis of the degree to which there may be risk of noncompliance with the IPPS-exclusion requirements. Existing hospitals, as well as new hospitals, would be included in the sample.

Appendix B contains an example of content that may be useful in communicating these priorities to applicants.

Appendix C contains the addresses for all of the AOs whose accreditation we have deemed for Medicare certification purposes. Please convey this information to prospective providers or suppliers who have the option of deemed accreditation. Please note that some AOs offer accreditation for provider types for which deeming is not an option (either because deeming is not permitted under the law, or because no AO has submitted an approvable application to CMS). Examples include nursing homes and dialysis facilities. For each AO in Appendix C we have listed the provider or supplier types for which the AO’s accreditation permits deemed status. If a provider or supplier type is not listed next to the name of a particular AO, then CMS does not deem such accreditation as meeting Medicare requirements.

Some provider types have the deemed accreditation option but an onsite CMS survey has been required to verify compliance with certain payment requirements related to exclusion from the inpatient prospective payment system (IPPS). The IPPS exclusion verification under 42 CFR 412 is a small but important aspect of the accreditation process for which the AO surveys are not deemed. To address this issue we are instituting a time-limited option process to treat the IPPS-exclusion verification for initial applications by signed attestation, the same manner in which such verification is handled for recertifications.

We hope this memorandum will assist States in both prioritizing survey work and in clearly communicating with providers and suppliers to understand:

• The reasons for CMS’ priority structure for survey and certification work;
• The options that providers or suppliers have to obtain a survey that can establish their qualification to participate in Medicare;
• The length of time that may elapse before they may be surveyed, with as much certainty as possible given the annual federal budget and resource uncertainties. A clearer sense of the timeline will help providers and suppliers in better planning their efforts.

We request that States make the priority structure in Appendix A, and the procedures for providers that have an AO option, widely known to the provider/supplier community as soon as possible.
We hope the Appendix B potential content may be useful to assist States in offering prospective Medicare providers and suppliers with as much relevant information and timeline clarity as possible.

If you have any questions concerning this memorandum, please contact your CMS Regional Office.

**Effective Date:** The information contained in this memorandum is applicable immediately for all healthcare facilities that rely on CMS survey and certification work. The State Agency should disseminate this information within 30 days of the date of this memorandum.

**Training:** This information should be shared with all appropriate survey and certification staff, surveyors, and the affected provider community.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
Appendix A
CMS Priorities for Initial Surveys of Providers and Suppliers Newly Enrolling in Medicare

I. Priority Exception Requests

*Access to Care Reasons:* Providers or suppliers may apply to the State survey agency (SA) for CMS consideration to grant an exception to the priority assignment of the initial survey if lack of Medicare certification would cause significant access-to-care problems for beneficiaries served by the provider or supplier. The State SA may choose whether to make a recommendation to CMS before forwarding the request to the CMS Regional Office (RO).

There is no special form required to make a priority exception request. However, the burden is on the applicant to provide data and other evidence that effectively establishes the probability of serious, adverse beneficiary health care access consequences if the provider is not enrolled to participate in Medicare. CMS will not endorse any request that fails to provide such evidence and fails to establish the special circumstances surrounding the provider’s request. We expect that such exceptions will be infrequent.

II. Accreditation Requests

SAs should continue to collect and forward to the CMS RO the certification packets\(^1\) for facilities wishing to participate in Medicare through deemed accreditation, including attestation documents for those facilities seeking first-time IPPS exclusion.

III. Tier 3

- **ESRD Facilities** – Due to the unique reliance of dialysis patients on Medicare, and the fact that there are no deemed accreditation options for ESRD facilities, we accord such facilities a higher (Tier 3) priority than most other provider or supplier types.

- **Transplant Centers** – Transplant centers are accorded the higher Tier 3 priority because there are no CMS-approved accrediting organizations (AOs) for transplant centers. While this may change in the future, CMS has neither received nor approved any AO applications for transplant center accreditation to date. In addition, transplant patients (and donors) rely on Medicare in ways that other patients do not (such as special eligibility provisions for post-operative immuno-suppressive drug coverage when certain otherwise ineligible individuals receive transplants from a Medicare-certified center).

- **Hospitals without an AO Option.** In this context it is necessary to distinguish the health and safety standards of the certification process for participation in Medicare from verification of compliance with the requirements for exclusion from the Inpatient Prospective Payment System (IPPS).
  - Verification of compliance with IPPS exclusion criteria by whole hospitals or excluded units of short term acute care hospitals is addressed in the discussion of Tier 4 priorities, part V of this Appendix.

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\(^1\) Such as the completed provider agreement, applicable civil rights forms, completed worksheets where necessary, copy of the accreditation letter from the AO, etc.
– Surveys for the special psychiatric conditions of participation (CoPs) found at 42 CFR 482.60 through 482.62 will be done as a Tier 3 priority, typically by a CMS contractor. While psychiatric hospitals in general are eligible for deemed accreditation, no AO is approved for verification of compliance for the special psychiatric conditions of participation found at 42 CFR 482.60 through 482.62. We expect that the rest of the hospital’s operations would achieve certification through deemed accreditation and that only the non-deemed part would be surveyed by the CMS as a Tier 3 priority.

– **Critical Access Hospital (CAH) Distinct Part Units:** A distinct part psychiatric or rehabilitation unit in a CAH must at this time rely on the higher Tier 3 priority, since the AO’s currently approved for CAH certification have not been approved for deeming relative to such units. We anticipate that renewal applications by AOs to continue their authority for the CAH program will cover these distinct part units in the future. Only the distinct part unit(s) is eligible for Tier 3 priority, while the rest of the CAH has a deemed accreditation option. We will advise SAs when an AO has been approved to deem the distinct part units.

Note: Conversions of an existing provider under the same provider agreement- is not considered an initial application and the priority for initials does not apply. The provider/supplier types in this circumstance are:

- Conversion of a hospital to a CAH, or a CAH back to a hospital is a conversion (not an initial certification), and at State option may be done as Tier 2, 3, or 4. However, the addition of swing beds as a new service in an existing hospital or CAH is a Tier 4 priority, the same as a new nursing home service would be if it were started by a non-hospital.
- Similarly, the conversion of a Medicaid-only Nursing Facility (NF) to dual-certification (SNF/NF) does not require an initial certification survey and may be done at the State’s discretion in accordance with SOM 7002.
- Nursing homes that convert to a Green House certified, resident-centered, culture change environment (which requires new construction).

**IV. Tier 4**

Accreditation Options: Initial certifications of all provider/supplier types that have the option to achieve deemed Medicare status by demonstrating compliance with Medicare health and safety standards through a survey conducted by a CMS-approved accreditation organization is a Tier 4 priority. In light of the federal Medicare resource constraints, we consider the cost of initial surveys to be the lowest priority for the Medicare program for those provider and supplier types that have a deemed accreditation option in those States unable to complete the higher-priority Tier 1-3 work.

Provider/supplier types with a Tier 4 priority for initial surveys because the have a deemed accreditation option include:

- Ambulatory Surgical Centers
- Home Health Agencies
- Hospices
- Hospitals
- Critical Access Hospitals
All Others: All other newly-applying providers/suppliers not listed in Tier 3 are Tier 4 priorities, unless approved on an exception basis by the CMS RO due to serious health care access considerations or similar special circumstances (see “Priority Exception Requests” above). The affected Medicare providers/suppliers include:

- Comprehensive Outpatient Rehabilitation Facilities
- Long Term Care Units in Hospitals
- Nursing Homes that do not participate in Medicaid
- Outpatient Physical Therapy
- Rural Health Clinics

V. Special Provisions for Compliance with IPPS-Exclusion Requirements

With respect to hospitals and CAHs, please note the following policy refinements:

1. Rehabilitation Hospitals: Rehabilitation hospitals are eligible for deemed accreditation, except for verification of the IPPS-exclusion requirements. Procedures for the IPPS-exclusion verifications are described below.

2. Psychiatric Hospitals: Psychiatric hospitals are eligible for deemed accreditation, except for the non-deemed special psychiatric CoPs at 42 CFR 482.60 through 482.62. While survey of the special conditions will be a Tier 3 priority for hospitals that have been otherwise deemed by an accreditation organization, survey for compliance with the rest of the hospital CoPs will remain a Tier 4 priority for CMS since the rest of the hospital survey may be accomplished by an AO.

3. IPPS-Excluded Rehabilitation Hospitals, and IPPS-excluded Rehabilitation or Psychiatric Units of a Hospital: Accreditation organizations do not have authority to verify a hospital’s or a hospital excluded unit’s compliance with the IPPS exclusion criteria at 42 CFR 412. Currently, annual re-verification of IPPS-exclusion for such excluded hospitals or units in already-certified hospitals is handled by provider self-attestation, but initial verification for first-time IPPS-exclusion has been required via certification surveys by the States.

Effective immediately we are suspending (until further notice) the requirement for an onsite IPPS-exclusion survey of all hospitals and units seeking first-time IPPS-exclusion (State Operations Manual (SOM) at section 3100 - 3108B), except for providers whose IPPS exclusion has previously been removed. Instead, such providers will be required to submit an attestation and completed Form CMS-437, CMS-437A or CMS-437B, whichever is applicable, indicating that all CMS exclusion requirements are met. Note that these attestation procedures apply to all hospitals and units that are IPPS-excluded.

In addition to the attestation and applicable Form CMS-437, rehabilitation hospitals and excluded rehabilitation units must also submit evidence of compliance with the medical director requirement. Psychiatric units must submit evidence of compliance with patient assessment and staffing requirements.

The following process will be used for IPPS-exclusion attestation and documentation:

(a) The SA will send to the provider the attestation statement and appropriate CMS-437, along with the standard packet of certification forms and documents, within 10 working days of the earlier of the following two dates:
• Receipt of the provider’s letter of intent to open for service and to seek IPPS exclusion; or
• Receipt of the Fiscal Intermediary’s recommendation for approval of the 855 application.

(b) In the case of rehabilitation hospitals or rehabilitation units, the SA will also request that the provider attach (to its completed certification packet) documentation that permits verification that the provider has a qualified medical director who meets the regulatory standards at 42 CFR 412.29(f).

(c) In the case of psychiatric units, the SA will also request that the provider attach to its completed certification packet the following information:
  • Medical record protocols to permit verification that each patient receives a psychiatric evaluation within 60 hours of admission; that each patient has a comprehensive treatment plan; that progress notes are routinely recorded; and that each patient has discharge planning and a discharge summary.
  • A description of the type and number of clinical staff, including a qualified medical director of inpatient psychiatric services and a qualified director of psychiatric nursing services, registered nurses, licensed practical nurses, and mental health workers to provide care necessary under their patients’ active treatment plans.

(d) The provider should return the completed certification packet, along with all other requested materials, to the SA no less than 90 days prior to the start of the facility’s first or next cost reporting period, as applicable, in order for the RO to have sufficient time to make a determination to approve or deny the provider’s IPPS exclusion status. If the provider submits the application less than 90 days in advance, CMS will continue to process the application, but the provider assumes the risk that the RO review may not be completed in time for payment at the excluded rate to start with the first or next cost reporting period.

(e) The SA will act promptly to review the completed packet and will forward it to the RO as soon as possible in order to permit a final certification determination prior to the start of the provider’s cost reporting period.

4. Psychiatric Unit or Rehabilitation Hospital/Unit IPPS Exclusion Removal: If CMS removes the IPPS exclusion status of a psychiatric unit or a rehabilitation hospital or unit, the hospital may subsequently seek excluded status again. In such cases the hospital is required to operate for at least twelve months under the IPPS while continuing to provide the applicable psychiatric or rehabilitation services that comply with the exclusion requirements. The facility must apply for IPPS exclusion status in the same way as a provider seeking first-time exclusion. However, in the case of a hospital or unit that has had its IPPS exclusion status removed, the requirement or onsite verification by the SA of compliance with the exclusion criteria for psychiatric or rehabilitation services will remain in force, and such surveys will be a Tier 4 priority.

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2 The twelve month requirement refers to the cost reporting period, and may be found at 42 CFR 412.25(c) and 412.25(f) for IPPS-excluded units of a hospital, and 42 CFR 412.23(h) and 412.23(i) for rehabilitation hospitals.
Appendix B - Example of Content for a Potential Provider Communication

Dear _____________

We appreciate your request to be certified for participation in the Medicare program. Due to very substantial federal resource limitations, we must currently adhere to a careful priority schedule as we respond to requests from providers that newly seek to participate in Medicare. We hope this letter is helpful to you in understanding your options in this difficult situation.

Two independent and important steps in becoming a Medicare provider are:

**Form CMS-855:** Form CMS-855 contains background, contact, service, and provider or supplier information that is essential to the approval process. The applications are reviewed and recommended for approval or denial by the Fiscal Intermediaries (FIs) or Medicare Administrative Contractors (MACs) under contract with the Centers for Medicare & Medicaid Services (CMS).

**Certification:** Most types of providers, and some suppliers, are required to demonstrate that they are in full compliance with Medicare quality and safety requirements. This demonstration is accomplished during an onsite survey conducted by trained and qualified surveyors from the State survey agency (SA) pursuant to an agreement with CMS. There is no charge to the provider or supplier for initial CMS surveys or any later CMS recertification survey. The CMS-855 must have been approved and the provider fully operational in order for a survey to be conducted.

Some provider/supplier types have the additional option to be accredited by a CMS-approved accreditation organization (AO), and such accreditation is “deemed” to be equivalent to a recommendation by the SA for CMS certification. The attached list provides contact information on each such AO, as well as information regarding the types of providers/suppliers for which deeming applies. Note that deeming does not apply to some provider types, such as nursing homes and dialysis facilities.

CMS instructs States to place a higher priority on recertification of existing providers, on complaint investigations, and on similar work for existing providers than for initial surveys of providers or suppliers newly seeking Medicare participation. **Due to severe resource limits for Medicare survey & certification functions, in most States few providers that have an AO option will be surveyed by CMS or the State.**

**Short-term acute care hospitals, rehabilitation hospitals, critical access hospitals (but not their distinct part psychiatric and rehabilitation units), home health agencies, hospices, and ambulatory surgical centers** all have the option of deemed accreditation. Applicants have the option of applying to one of the CMS-approved AOs. The attachment to this letter conveys the requisite contact information.

Providers may apply by letter to the SA for CMS consideration to grant an exception to the priority assignment of the initial survey if lack of Medicare certification would cause significant access-to-care problems for Medicare beneficiaries served by the provider or supplier. The SA may choose whether to make a recommendation to CMS before forwarding the request to CMS.
There is no special form required to make a priority exception request. However, the burden is on the applicant to provide data and other evidence that effectively establishes the probability of adverse beneficiary health care access consequences if the provider is not enrolled to participate in Medicare. CMS will not endorse any request that fails to provide such evidence and fails to establish the special circumstances surrounding the provider’s or supplier’s request.

CMS recognizes that special circumstances apply to certain types of providers or suppliers, and has made special priority allowances for them. Both dialysis facilities and transplant centers, for example, are afforded a higher priority compared to certain other providers/suppliers because there is no AO option available, end-stage renal disease patients and transplant patients have a unique reliance on Medicare for their care, and access is often an issue.

Hospitals that are applying for rehabilitation hospital status or for an IPPS-excluded unit(s) for rehabilitation and/or psychiatric services and that have (or will have) attained AO accreditation from a CMS-approved AO for their general hospital operations will be allowed to submit an attestation of compliance with Medicare requirements by their PPS-excluded unit(s). In addition, they will be required to complete a Form-437, Form-437A, or Form-437B, as applicable, in addition to the attestation. This will avoid the need for both an AO accreditation survey and an on-site PPS-verification survey by an SA, since there is no AO option for verification of such IPPS-excluded units. If you are in this situation, please communicate with the SA as early in the process as possible.

We regret that the resource limitations under which we operate may complicate the process of enrolling in Medicare as a certified provider or supplier.
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<td>Kurtz, Trisha</td>
<td>601 13th Street, NW Suite 1150N Washington, D.C. 20005</td>
<td>202-783-6655</td>
<td>202-783-6888</td>
<td><a href="mailto:pkurtz@jcaho.org">pkurtz@jcaho.org</a></td>
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<td>One Renaissance Boulevard Oakbrook Terrace, IL 60093</td>
<td>630-792-5785</td>
<td>630-792-4885</td>
<td><a href="mailto:ksteffens@jcaho.org">ksteffens@jcaho.org</a>, <a href="mailto:mpeck@jcaho.org">mpeck@jcaho.org</a></td>
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<td>142 East Ontario St Chicago, IL 60611-2864</td>
<td>312-202-8060</td>
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<td>90 West County Rd C Suite 300 St. Paul, MN 55117</td>
<td>651-487-2806</td>
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<td>American Association of Blood Banks (AABB) Labs Sullivan, Judy Rapp, Holly</td>
<td>Bethesda, MD 20814</td>
<td>301-215-6540</td>
<td><a href="mailto:jsullivan@aabb.org">jsullivan@aabb.org</a></td>
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<td></td>
<td>301-215-6523</td>
<td><a href="mailto:Holly@aabb.org">Holly@aabb.org</a></td>
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