Under section 484.50, you listed the only reasons a patient can be discharged. As the Wound RN, part of my job is to see that our patients continue to make improvement toward healing in a reasonable manner. We see a certain number of patients who, even with good care & close management by a Wound Clinic, do not progress. We have never been allowed to "maintain" chronic wounds because of the rule that we show improvement. Having kept patients on service for 1-2 years, what do we do if the MD won't discharge from Home Health?

Although the Medicare contractors erroneously denied claims based on “no improvement,” a recent lawsuit resulted in clarification by CMS of the longstanding Medicare statute and regulations that allow for ongoing skilled medically necessary care to homebound beneficiaries, regardless of whether their condition is acute, chronic, long term or terminal. Therefore, if you can demonstrate through documentation that the wound requires the skills of a nurse and the care ordered and provided is appropriate and meets clinical practice standards, then the patient may receive home health services indefinitely. See the following from MLN Matters at http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/mm8458.pdf.

“In accordance with the Jimmo v. Sebelius Settlement Agreement, the Centers for Medicare & Medicaid Services (CMS) has agreed to issue revised portions of the relevant program manuals used by Medicare contractors, in order to clarify that coverage of skilled nursing and skilled therapy services “…does not turn on the presence or absence of a beneficiary’s potential for improvement, but rather on the beneficiary’s need for skilled care.” Skilled care may be necessary to improve a patient’s current condition, to maintain the patient’s current condition, or to prevent or slow further deterioration of the patient’s condition.”

Explain the new HHA supervision you spoke about.

If finalized as proposed, aide supervision requirements will be more detailed than they currently are. It would be most helpful to provide the actual proposed regulation for aide supervision:
(h) Standard: Supervision of home health aides.

(1) (i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a registered nurse or other appropriate skilled professional described in paragraph (g) of this section must make an onsite visit to the patient’s home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

(ii) If a potential deficiency in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete a competency evaluation in accordance with paragraph (c) of this section.

(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient’s plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient’s condition; and

(vi) Honoring patient rights.

Where can the QAPI tools be obtained?

Finally, CMS referenced the accrediting agencies (e.g. JC, CHAP) as have quality assessment requirements that exceed the proposed rule requirements and can serve as sources for QAPI guidance.

**Is a Home Health Agency required to do QAPI every quarter?**

CMS intends to remove the quarterly record review requirement. In its place, a CMS will require an “ongoing” QAPI program that includes “Performance improvement projects. The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA’s services and operations.”

**Is there a timeframe with regard to sending the discharge summary?**

CMS proposed a specific timeline but did ask for comments as to whether the 2 day of transfer requirement is appropriate. The proposed rule reads:

“A completed discharge or transfer summary, as required by §484.60(e), that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 7 calendar days of the patient’s discharge; or, if the patient’s care will be immediately continued in a health care facility, a discharge or transfer summary is sent to the facility within 2 calendar days of the patient’s discharge or transfer.”

**The copy of the POC that is required to be in patient home folder - is there specificity that POC copy is a signed copy by MD?**

Questions remain as to what CMS will require to meet that “each patient would also have the right to receive a copy of his or her individualized HHA plan of care.” Comments were submitted to CMS suggesting that the physician plan of care that contains medical terminology and acronyms may not be appropriate for patients. Rather they should receive documentation of disciplines and frequency of visits. A physician signed plan of care was not mentioned in the proposed rule.
Since the QAPI is governing Board members involvement - are the PAC meetings going away? If so, can we do away with the PAC now or must the final rule be approved first?

CMS proposes to replace “group of professional personnel” (i.e. PAC) with the QAPI program which must have Board oversight and direction. PAC meetings will no longer be required.

Will the 60 day summary requirement be removed?

The rule proposes removal of the 60 day summary requirement. Home health agencies will be required to:

(1) “…promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient’s progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.”

When an LVN goes to see a patient and there is a change in condition such as new wound, or infection etc. does the RN need to follow up as it will require a comprehensive assessment?

Current regulation requires a comprehensive assessment when there is a “significant change” in a patient’s condition. Development of a wound may or may not constitute a significant change. Comments were submitted to CMS requesting they review the regulatory language which suggests that every change in orders must be accompanied by a comprehensive assessment. We must wait to see whether they revise this rule.

Can the OT be the only discipline in the case management of the patient care?

Medicare coverage policy limits management and evaluation of the plan of care to the registered nurses.
Does this mean that when changes are made, we must send a new 485 every time?

Completion of a new Plan of Care (often referred to as a 485) would not be required for new or revised interim orders during a 60 day episode. CMS considers interim orders as revisions to a plan of care.

**In reference to Infection Control education to patients and caregivers, is that annually as well?**

CMS intends that home health agencies provide ongoing infection control education for patients under their care as part of their infection control program.

**In reference to Administrator qualifications, will they grandfather in those of us that don't have an undergraduate degree. The regulation used to say "preferably."**

CMS did not address whether they would grandfather current administrators who are not physicians or RNs and who do not hold a degree.

**Please define what "care preferences identified by the patient" means.**

CMS does not define or provide elaboration of patient “care preferences.”

**As per regulation 484.60 in regard to verbal orders, if an LPN takes a verbal order, should the RN be co-signing these?**

The regulations relating to verbal orders remain unchanged from current requirements. Currently verbal orders that are not taken by the RN or therapist who is caring for the patient or supervising patient care must be reviewed and signed by the caring or supervising RN or therapist. The current regulation reads:” Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in §484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA’s internal policies.”
Regarding, 484.60, if an agency is discharging a client to the community with no formal assistive services, there is no plan of care. This seems to direct the agency to still provide comprehensive assessment data to the physician at this time. Is that correct?

The regulation does not specify comprehensive assessment. The discharge summary must be a summary of the patient's stay, including the reason for referral to the HHA, the patient’s clinical, mental, psychosocial, cognitive, and functional condition at the time of the start of services by the HHA, all services provided by the HHA, the start and end date of care by the HHA, the patient's clinical, mental, psychosocial, cognitive, and functional condition at the time of discharge from the HHA, an updated reconciled list of medications at the time of discharge or transfer, and any recommendations for ongoing care (for example, outpatient physical therapy); (2) The patient's current plan of care, including the latest physician orders; and (3) Any other documentation that will assist in post-discharge or transfer continuity of care, or that is requested by the health care practitioner who will be responsible for providing care and services to the patient after discharge from the HHA or receiving facility.

Regarding 484.75, my agency contracts with several therapy companies. Are these subcontracted entities required to participate in Agency in-service programs?

Although not specifically stated, it is implied since contracted individuals must be skilled professionals and the regulation states that skilled professionals must participate in agency sponsored in-service education.

Regarding 484.100, would this also include point of care testing such as INRs?

It is very possible that equipment for monitoring INR may be an exception to the rule requiring use of patient equipment because of the limited coverage and requirements for patient self-monitoring as follows:

“Home prothrombin monitoring with the use of INR devices is covered only for patients with mechanical heart valves. The monitor and the home testing must be prescribed by a treating physician as provided at 42 C.F.R. 410.32 (a) and the following requirements must be met:”

1. The patient must have been anticoagulated for at least three months prior to use of the home INR device;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home”
Regarding "supervised practical training" under supervision of RN; does this mean limit supervision needs by done by RN rather than therapists? What about therapy only cases?

Yes, the RN or LPN under the supervision of the RN must conduct aide supervised practical training. The regulation reads:

(b) Standard: Content and duration of home health aide classroom and supervised practical training. (1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse.

Regarding 484.60, does Plan of Care refer to what we know as the 485? Is the Plan of Care different from Care Plan?

Yes. The 485 was once a required form for documenting the home health plan of care. CMS no longer requires use of the 485. Therefore, home health agencies may use a format of their choice for documenting the plan of care, as long as all required fields are included.

Will the new COPs allow nurse practitioners to order home care services?

Unfortunately Congress must pass legislation to authorize extension of ordering of home health services to practitioners other than physicians. Therefore, CMS is unable to make this change through regulation.

When will these go in to effect? When they are finalized in three years? Or sooner?

This is still in proposed rule form. One source recently said that CMS now hopes to publish the final regulations before the end of 2015. Once published, home health agencies will likely have at least 90 days to implement them (possibly as long as 120 days for certain requirements) if CMS meets its goal.

Are agencies that only provide Medicaid services required to be Medicare-certified?

Yes, Medicare certification is required for agencies that provide Medicaid skilled services. However, it is not required for limited personal care programs under Medicaid.
Is there still a 65 mile requirement for "branch supervision?"

CMS eliminated the distance requirement for branch offices several years ago. However, some States continue to maintain a mileage limit.

Does "plan of care content" mean the description of risk for ED or hospital re-admission (low, medium, high) has to be included on the 485 Plan of Care?

In comments to the proposed rule it was suggested that risk assessment be part of the comprehensive assessment. It is possible that in writing the regulation CMS misrepresented their intent based on the Federal Register preamble which clearly differentiates between assessment and care plan requirements as follows:

“If HHA services are initiated following a patient’s hospital discharge, we propose to require that the HHA must include an assessment of the patient’s level of risk for hospital emergency department visits and hospital re-admission. In order to establish the patient’s risk level, we believe that HHAs would identify the patient’s specific risk factors. We propose that HHAs would be required to include in the patient’s individualized plan of care all appropriate interventions that are necessary to address and mitigate those identified risk factors that contribute to the HHA’s establishment of a particular risk level for a patient.”

Are current subunits going to be grandfathered in or what is the plan?

Since subunits must meet CoPs independently, and are therefore treated as independent home health agencies under federal regulation, CMS is merely eliminating the term subunit. However, home health entities will not be prevented from having a corporate structure that includes subunits.

When discharging patient for cause; would the ABN form serve as a documented effort to resolve the problem?

The ABN would be insufficient to meet CMS’ expectations for documenting discharge for cause.

CMS requirements are detailed in the Federal Register preamble as follows:
“Before discharging a patient for cause, the HHA would be required to advise the patient, the representative (if any), the physician who is responsible for the home health plan of care, and the patient’s primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause was being considered, make efforts to resolve the problem(s) presented by the patient’s behavior or by other person(s) in the home (as applicable), or situation (such as a dangerous animal being loose in the home), document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records.”

Will these comprehensive assessment components such as strengths, personal goals, and care preferences be identified in the OASIS document changes?

The only OASIS changes CMS has planned at this time are those related to ICD-10. Home health agencies will be expected identify means for documenting these elements in the comprehensive assessment.

It was not mentioned if Clinical Record Review has been removed from the Quality program.

You are correct in stating the clinical record reviews have been removed. In the proposed rule notice CMS stated that “the prescriptive quarterly review of clinical records is outdated and unnecessary.” Rather CMS goes on to say that “There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care. Each professional may review the records separately, at different times.”

Is this rule final yet? If not, what is the date for final rules?

This is still in proposed rule form. One source recently said that CMS now hopes to publish the final regulations before the end of 2015. Once published, home health agencies will likely have at least 90 day to implement them.

If on our Home Health consent form we have the statement "I have been fully informed of my rights and responsibilities" and they sign the consent and not a separate clients rights form, would that be acceptable?
The regulatory language reads: “Obtain the patient’s or representative’s signature confirming that he or she has received a copy of the notice of rights and responsibilities.” There is no prohibition on statement being combined with other consents.

**Will QAPI replace OBQI or in addition to?**

The intent is for OBQI to be a part of home health agency QAPI programs.

**When you say removed, would it apply now or until the federal rule is finalized?**

Regulations will not be removed or revised until and if finalized. Home health agencies must continue to comply with all current CoP.

**Do you know if anyone from CMS or any other agency will be putting on any sort of education conferences or seminars for additional guidance and clarification for Home Health agencies regarding the Conditions of Participation once they are finalized and published in the Final Rule?**

In view of CMS’ recent history, they will likely provide webinars and other guidance on the CoPs once finalized.