

Comments for CMS Draft Conditions of Participation (CoPs) Interpretive Guidelines (IG)

***Overarching concerns:***

State Operating Manual

Without knowing how CMS will update the State Operations Manual (SOM), which instructs surveyors on the probes to use to measure compliance, it is difficult to offer detailed comments and even more difficult to design a compliance plan to support compliance with the CoPs.

The IG should provide "survey procedures" for all sections where updates and/or changes have been made to the CoPs.

Software and Data Compliance

Without survey procedures and guidance, providers are unable to provide software partners with meaningful input regarding software modifications required to support compliance.

***Specific Interpretive Guidelines that need more detail / clarification / or specificity:***

**Interpretive Guidelines §484.50 (a)(1)(iii): An OASIS privacy notice to all patients for whom the OASIS data is collected.**

Please provide clarification about some of the deadlines for patients that where English is not their primary or preferred language.

**Interpretive Guidelines §484.50(a)(2): Obtain the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.**

Please clarify that this guideline requires either the patient's signature or, in the case where a legal representative exists, his/her signature. The guidance reads as if there is an additional patient representative.

Further, add the word "legal" to the statement "patient representative" throughout the Interpretive Guidelines for consistency and clarity.

**Interpretive Guidelines §484.50(a)(3): Provide verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the second visit from a skilled professional as described in §484.75.**

The requirement to provide the patient's bill of rights by the second visit to is potentially burdensome to the patient in the cases where the second visit may actually occur in the same day (IV, wound care, etc.) and / or in cases where the patient is in a very rural, difficult to access area with limited electronic and telephonic services. In these circumstances, it would be better for the patient to get their needed care and provide the translation of all the rights within a more expanded timeframe (i.e. within five days or three visits).

Also, please clarify the contradiction between:

- 484.50(a)(3) Interpretive Guideline statement says that a "delay in notification in instances where an HHA patient speaks a language which the HHA has not translated into written material no later than the second visit", and
- 484.50 (a)(1) which states where agencies must provide the patient and the patient's representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient.

**Interpretive Guidelines §484.50(a)(4): Provide written notice of the patient’s rights and responsibilities under this rule and the HHA’s transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.**

There are no explanatory narrative portion to the interpretive guidelines for this section. Please clarify whether a summary of policies would meet this requirement. Providing full printed copies of all policies would be hard for patients to read and burdensome to agencies and could be accomplished under request.

**Interpretive Guidelines §484.50 (b) Standard: Exercise of rights.**

For consistency this should say the patient's *legal* representative.

**Interpretive Guidelines §484.50(c)(1): Have his or her property and person treated with respect;**

The Interpretive Guidelines call for the agency to ensure that the patient’s property is safe from damage or theft “during a home visit.” This should be restricted to damage or theft *caused by HHA personnel*. The guidelines need to limit the HHA's responsibility to their own staff. The Interpretive Guidelines language could state that the HHA takes appropriate action to train HHA regarding the respect of patient property and follows up on any related patient complaints if made in accordance with the section on patient complaints.

**Interpretive Guidelines §484.50(c)(4): Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate**

CMS should ensure that adequate education of surveyors. In the past, surveyors taken a more stringent view between patient’s rights or choice and the tasks on the HHA aide assignment sheets.

**Interpretive Guidelines §484.50(c)(5): Receive all services outlined in the plan of care.**

Please provide clarification and narrative for documentation of patient refusal of care and subsequent adjustments to the plan.

**Interpretive Guidelines §484.50(d)(2): The patient or payer will no longer pay for the services provided by the HHA**

Please clarify if discharge for when the payer or patient will no longer pay includes not meeting the face to face requirement. There are 30 days after the physician start of care to complete this requirement.

**Interpretive Guidelines §484.50(d)(7): The HHA ceases to operate.**

Please provide confirmation that “sufficient notice” should be interpreted as 30 days’ notice.

**Interpretive Guidelines §484.55(a)(1): A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.**

CMS has stated that the HHA should visit at the patient's convenience. This should be included in this section to indicate why an initial visit could not be made within 48 hours of referral or return home. Further, the guide should be less prescriptive and thereby allow the physician flexibility based on his prioritization of the patient need by allowing a date range - within the next four (4) days - or beginning the week of xxx - rather than an actual exact date.

**Interpretive Guidelines §484.55(a)(2): When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.**

Please confirm that an occupational therapist can perform a Start of Care (SOC) OASIS assessment when the only service ordered by the physician is occupational therapy.

**Interpretive Guidelines §484.55(c)(1): The patient's current health, psychosocial, functional, and cognitive status**

For some states, assessing a patient's psychosocial status includes a mental health evaluation within the community. A mental health evaluation needs to be made by a mental health practitioner. This is beyond the scope of a visiting nurse or therapist practice if more is required than currently exists in the OASIS or as under the care plan content section the reference to orientation to day and time.

**Interpretive Guidelines §484.55(c)(4): The patient's medical, nursing, rehabilitative, social, and discharge planning needs**

Please provide clarification of "social needs."

**Interpretive Guidelines §484.55(c)(5): A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.**

The medication management guidelines discuss communications with physician, please provide needed guidance on expectations for the nurse. Further, please confirm if this guideline allows capable therapists (PT) or pharmacists arranged by the agency to review the list of medications.

**Interpretive Guidelines §484.55(c)(6): The patient's primary caregiver(s), if any, and other available supports, including their:**

**(i) Willingness and ability to provide care, and**

**(ii) Availability and schedules;**

No guidance is offered on how to successfully determine the caregiver's availability and schedule during the comprehensive assessment. CMS should specify what is expected from the provider. It should be sufficient that agencies document the general time of day/week that the caregiver is in the home with the patient.

Pediatric home health providers are often asked by health plans to manage parent work schedules so that care from the agency does not overlap care being provided by informal supports. This puts strain on HHA personnel to monitor families.

**Interpretive Guidelines §484.55(d): The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than--**

Please provide further clarification and/or additional examples to assist providers with designing training programs to educate and support compliance in this area.

**Interpretive Guidelines §484.55(d)(1): The last 5 days of every 60 days beginning with the start-of-care date, unless there is a:**

- (i) Beneficiary elected transfer;**
- (ii) Significant change in condition; or**
- (iii) Discharge and return to the same HHA during the 60-day episode.**

The Interpretive Guidelines state that "the update of the comprehensive assessment may be performed any time up to and including the 60th day from the previous assessment. The subsequent 60-day period would then be measured from the completion date of the last update" and 484.60(c)(1) states "the revised plan of care is sent to the responsible physician for review and approval which restarts the 60-day period for review of subsequent plans of care". Are subsequent 60-day periods changed due to a Significant Change in Condition?

**Interpretive Guidelines §484.55(d)(2): Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician-ordered resumption date;**

Please provide guidance on how to comply with timing compliance when resumption of care is ordered by a new physician.

**Interpretive Guidelines §484.60: Condition of participation: Care planning, coordination of services, and quality of care.**

The interpretive guidelines need to note that the "individualized written plan of care" in 484.60 is different from the "individualized plan of care" in section 484.60(a)(2).

Specification from CMS as to the extent and type of written information that should be provided to the patient should be added to the Interpretive Guidelines §484.60. In response to an email from HCA of NY

requesting CMS' confirmation that agencies are not required to give their patients a copy of the plan of care as stated in 484.60, CMS responded:

*Section 484.60(e) requires HHAs to provide each patient with written information regarding:*

*(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.*

*(2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.*

*3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.*

*(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.*

*(5) Name and contact information of the HHA clinical manager.*

*By contrast, 484.60(a) requires that the home health plan of care must include the following:*

- *All pertinent diagnoses;*
- *The patient's mental, psychosocial, and cognitive status;*
- *The types of services, supplies, and equipment required;*
- *The frequency and duration of visits to be made;*
- *Prognosis;*
- *Rehabilitation potential;*
- *Functional limitations;*
- *Activities permitted;*
- *Nutritional requirements;*
- *All medications and treatments;*
- *Safety measures to protect against injury;*
- *A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.*
- *Patient and caregiver education and training to facilitate timely discharge;*
- *Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;*
- *Information related to any advanced directives;*
- *Any additional items the HHA or physician may choose to include; and*
- *All patient care orders*

*We do not believe that the written information described in 484.60(e) is at all equivalent to the plan of care described at 484.60(a).*

**Interpretive Guidelines §484.60 (a)(1): Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and**

goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration.

If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Patient measurable outcomes may include such measurements as end-result functional and physical health improvement/stabilization, health care utilization measures (hospitalization and emergency department use), and potentially avoidable events.

The guidance says the physician decides if the patient visit may be skipped. This is new and not practical. If the patient refuses or isn't available, the visit has to be skipped. Agencies currently do not consider it a missed visit until we have no more opportunity to make up that visit within the Medicare week.

Please clarify if the Significant Change in Condition (SCIC) OASIS, currently called 'Other F/U OASIS,' needs a new assessment and plan of care and would start a new the 60-day certification period beginning from the date of SCIC?

**Interpretive Guidelines §484.60 (b)(2): Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient to determine for the screening contraindications. The administration of these vaccines is an exception to §484.60(b)(1).**

The sentence "No individual physician order is required for the vaccine" in the narrative should be modified to include - "unless required by State law."

**Interpretive Guidelines §484.60(c)(1): The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) 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.**

Interim changes in physician orders and the plan of care do not automatically restart the timeframe for physician review of the plan of care. However, if there is a significant change in the patient's condition and the services to be provided by the HHA, the revised plan of care is sent to the responsible physician for review and approval which restarts the 60-day period for review of subsequent plans of care.

**Interpretive Guidelines §484.60 (a)(3) & (c) (2):**

**§484.60(a)(3) All patient care orders, including verbal orders, must be recorded in the plan of care.**

**§484.60(c)(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.**

Please provide clarity on these guidelines. Agencies do not create a "revised" plan of care after the initial plan of care is created and signed by the physician. All verbal orders must be recorded in the plan of care. Agencies add the updates and orders are in the electronic medical record.

**Interpretive Guidelines §484.60(c)(3)(i): Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians issuing orders for the HHA plan of care.**

The Interpretive Guidelines are inconsistent with the regulations and should be revised. As stated in 42 CFR 424.22 any revisions to the plan of care were communicated to “all physicians issuing orders for the plan of care,” while the Interpretive Guidelines indicate that “all relevant physicians providing care to the patient” have been informed of changes to the plan of care.

**Interpretive Guidelines §484.60(d)(1): Assure communication with all physicians involved in the plan of care.**

When discussing coordination with all physicians, this guideline overlooks coordination with APRNs or PAs who might be part of the care of the patient – not only in this section but in many sections discussing care coordination.

The standard of “physicians who give orders that are directly related to home health skilled services” is unclear and needs to be clarified. Many patients have medications written by several physicians. Sometimes, the supervising physician will sign for all medications; other times, that physician does not. Nonetheless, all medications are part of the patient’s plan of care and reviewed, checked for interactions and side effects, and taught to the patient. However, if there are no medication interactions there is no need to coordinate with every prescriber.

**Interpretive Guidelines §484.60(e): Standard: Written information to the patient. The HHA must provide the patient and caregiver with a copy of written instructions outlining:**

As HHAs and other health care providers are being encouraged to invest in technology and utilize electronic records, these requirements will add a tremendous amount of materials that agencies will have to develop and distribute to consumers and family members. Consumers can be overwhelmed by so much paperwork and requiring that it be discussed with the patient is more productive, with the option of written information, if requested.

**Interpretive Guidelines §484.60(e)(2): Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.**

Capable therapists (depending on the type of medications) and pharmacists should be allowed to conduct medication reviews within their scope of practice.

**Interpretive Guidelines §484.60(e)(4): Any other pertinent instruction related to the patient’s care and treatments that the HHA will provide, specific to the patient’s care needs.**

Please add narrative to the guideline to provide examples or scope of "any other pertinent instruction related to the patient's care."

**Interpretive Guidelines §484.75(c): Standard: Supervision of skilled professional assistants.**

Please clarify what is meant in the guideline narrative by “communication and oversight” and patient’s “response to services.” Also, please provide an example or clarification of “adequate documentation”.

Documentation in the clinical record should show how communication and oversight exist between the skilled professional and assistant regarding the patient's status, the patient's response to services furnished by the assistant, and the effectiveness of the written instructions provided to the assistants.

**Interpretive Guidelines §484.75(c)(1): Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).**

This condition is related to the RN supervision of care provided by Licensed Practical/Vocational Nurses, however the last sentence of the Interpretive Guideline states "only the skilled therapist may perform comprehensive assessment, evaluation, care planning and discharge planning". Please provide clarification as to whether it should state "registered nurse", instead of "skilled therapist."

**Interpretive Guidelines §484.75(c)(2): Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(e, f) or (g, h), respectively.**

Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(e, f) or (g, h), Please clarify what is meant by "supervision of services" by an RN to an LPN and by a therapist to a therapy assistant. Additionally, please clarify if there an expectation that the overseeing RN or therapist visits the patient when the skilled professional assistant is not present (or just the skilled professional assistant is to visit).

**Interpretive Guidelines §484.75 (c)(3): Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).**

This condition is related to the supervision of care provided by social worker, however the last sentence of the Interpretive Guideline states "only the skilled therapist may perform comprehensive assessment, evaluation, care planning and discharge planning". Please provide clarification as to whether it should state "registered nurse", instead of "skilled therapist."

**Interpretive Guidelines §484.80(c) Standard: Competency evaluation. An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.**

Please confirm that the competency evaluation referred to in this rule is the one taken immediately following their HHA training or is the upon hire competency evaluation that is done by the hiring agency.

**Interpretive Guidelines §484.80(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x), and (b)(3)(xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.**

Please provide clarification for between the Interpretive Guideline:

- (A) Sponge, tub, **and** shower bath, and
- (B) Hair shampooing in sink, tub, **and** bed.

And

The State Operations Manual stated:

- (B) Sponge, tub or shower, and
- (C) Shampoo, sink, tub or bed.

Please provide clarification on which guide has precedence.

**Interpretive Guidelines §484.80(g)(3)(iv): The duties of a home health aide include:**

**(iv) Assistance in administering medications ordinarily self-administered.**

Assistance in administering medications has been defined under State Law in many states and more expansive than just bringing water to the patient and may include bringing the pill bottle or medication planner to the patient, reminding the patient to take the medications, opening a bottle that is difficult for the patient to open, etc. This Interpretive Guideline needs to be expanded to allow for that level of additional assistance as not to further burden patients.

The state Home Health Scope of Tasks can define Self-Administration of Medication differently and permits much more than this and is further extended for self-directing patients.

Examples include guidance from New York state saying:

Oral Medications: HHAs can prompt the patient to take medication, read the label, bring medication and supplies to patient, open the container for the patient, position patient for medication administration, (Special Circumstances: remove proper amount of medication, put medication in mouth), dispose of used supplies, clean reusable equipment, store medication properly, observe, record, report.

HHAs can also assist with topical medications for stable skin surfaces, injectable medications (basically set up and disposal, storage).

**Interpretive Guidelines §484.80 (g)(4): Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.**

The Home Health Aides at Interdisciplinary group / team meeting (IDG or IGT) guidelines states that all HHA staff must be present, but the HHA aide may participate in person electronically or via phone.

Please clarify that the home health aide can submit or communicate their updates via coordination notes or conversation with the case manager prior to the meeting and does not have to attend in real time during the IDG meeting.

In many states, many home health aides are contract vendors who work for a separate agency and not the HHA and are not available for team meetings.

**Interpretive Guidelines §484.100 (c)(1): If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter.**

Please clarify these guidelines as PT/INR testing will likely not ever be self-administered by the patient.

**Interpretive Guidelines §484.102 (a)(3): Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.**

Please provide guidelines specific to home health care.

**Interpretive Guidelines §484.102(b)(1): The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at §484.55.**

The guidelines need to clarify if it is enough to provide the emergency preparedness plan only to the patient if the patient is alert and oriented. Further clarify when would the HHA be required to provide the plan to a caregiver, and how is caregiver defined for this purpose.

**Interpretive Guidelines §484.102(c): Communication plan. The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:**

As evidenced by recent natural disasters, shouldn't a communications plan due to lack of internet or cell coverage for everyone not just in rural or areas with limited connectivity.

**Interpretive Guidelines §484.105 (b)(1): The administrator must:**

- (i) Be appointed by and report to the governing body;**
- (ii) Be responsible for all day to day operations of the HHA;**
- (iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;**
- (iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.**

Please clarify if agencies need to change their corporate reporting structure, those with a larger corporate structure have Administrators that report up to a VP and CEO who then reports to the board.

**Interpretive Guidelines §484.105(d) Standard: Parent branch relationship:**

- (1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.**
- (2) The parent HHA provides direct support and administrative control of its branches. A branch office is a location, physically separate from the parent location, from which an HHA provides services under the same certification number as the parent agency. The parent location provides supervision and administrative control of branch offices on a daily basis to the extent that the branch depends upon the parent's supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity.**

The Interpretive Guidelines should detail what is expected for a parent to provide supervision and administrative control on a “daily basis.” In addition, it is not clear how to measure “the extent that the branch depends upon the parent’s supervision and administrative functions in order to meet the CoPs.” For example, if a branch has its own clinical manager, it is appropriate for the parent to be uninvolved in the daily aspects of the clinical manager’s role and the CoPs that relate to the clinical manager function.

While subunits are being eliminated, the Interpretive Guideline provides no clear guidance on the specific steps an agency is required to take, if any, to convert the subunit to a new parent agency. While this information may ultimately be contained in the SOM, without timely guidance HHAs are left to assume (and hope the assumption is correct) that no affirmative steps are required to support the conversion process.

**Interpretive Guidelines §484.110 (e) Standard: Services under arrangement.**

Please confirm that the provider is only expected to provide the clinical record from the previous visit and not providers expected to retrieve and provide the patient with a copy of his/her entire clinical record.

Additionally, With the distance that some clinicians have to travel back and forth to the agency, it is not practical that they could deliver the patient's medical record the next business day. Please confirm that emailed hard copy sent within 24 hours is sufficient and meets the requirement.

**Clarification or Considerations Not Captured by Interpretive Guidelines**

*Full consideration of clinicians in Care Coordination:*

When discussing coordination with all physicians, these guidelines miss coordination with APRNs or PAs who might be part of the care of the patient.

*Pediatric patient considerations:*

In many states, the CoPs apply to home health agencies that are providing care to pediatric patients. These agencies are required by the state to be Medicare-certified even though this care is not reimbursed by Medicare. This creates many areas of inconsistency with the CoPs that the Interpretive Guidelines do not address. For example:

- 484.50(d)(10): information provided to the patient includes the Area Agency on Aging, which will never be applicable to a pediatric patient
- 484.60(a)(2)(xii): pediatric patients are consistently at risk for hospitalization, based solely on their complex needs and this is often outside the control of the agency. In addition, subsection (xiii) discusses plans for a timely discharge, yet it is not anticipated that these children will be timely discharged. While a provider may wean the child from dependence on ventilation or other interventions, the Interpretive Guidelines should give surveyors guidance on patients for whom a physician does not anticipate a discharge from home health services.

*Clarification on the differentiation of terms:*

The CoPs at times deliberately differentiate between information that needs to be “communicated” versus “written” and instances where the patient or representative needs to be “notified” about some aspect of care. These terms should be defined so that agencies know, for instance, when it is appropriate to document that a conversation took place or ask the patient/family to sign a record showing that they were notified of a change.

The interchangeability of these terms will lead to confusion and misinterpretation. The Interpretive Guideline §484.60(c)(3)(i) is a key instance of confusion between *notified*, *communicated to*, and *shared with* are used interchangeably.

Another term that the Interpretive Guidelines use interchangeably but the CoPs seem to purposefully distinguish is “representative.” In the Interpretive Guidelines for 484.50(a)(1), it says “When there is no evidence of a guardianship...the information should be provided to the patient.” Yet, just above it states that the patient should determine his/her own representative who should also receive patient rights information.

Since the Interpretive Guidelines say to give information to the patient directly where there is no legal representative, are agencies still expected to give the information to a patient-designated representative if the patient wishes? How far does the responsibility go?

It would be helpful if the Interpretive Guidelines used the terms patient-selected representative and legal representative throughout, rather than just “representative,” so agencies understand the protocol.

#### *Emergency Preparedness:*

Throughout the emergency preparedness guidelines there is discussion of “facility”. Home health agencies don’t have facilities. Need guidance specific to home health agencies or an exemption.

#### *Transition process for agencies to transition subunits into branch locations:*

Please provide guidance, either by Survey & Certification letter or other means, to detail the process for agencies to transition subunits into branch locations. Members have heard from state surveyors that this might be done automatically, but they are awaiting clarification from CMS before moving forward.