

# State Operations Manual, Appendix B – Guidance for Surveyors: Home Health Agencies (HHAs)

Rev. 4-16-2024

On March 15, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a revised State Operations Manual, Appendix B – Guidance for Surveyors: Home Health Agencies (HHAs), commonly referred to as the interpretive guidelines (IGs) to the Conditions of Participation (CoPs).

The revised Appendix B begins with survey protocols and adds survey procedures under many of the standards to assist surveyors in assessing compliance with the regulatory requirements.

CMS has updated all applicable IGs to incorporate regulatory amendments to the HHA CoPs since the last issuance of Appendix B, along with modifications to the IGs that reflect stakeholder input. HHAs should review the additions/revisions closely for survey preparation.

The first column lists the CoP (highlighted in blue) along with each standard, the second column indicates whether there has been any change in the IGs for that CoP or standard, and the third column list the CoP and standards along with any corresponding changes to the IGs. Also included is the G-tag range for that CoP.

PRIOR VERSION

CHANGES REVISED VERSION

## Subpart A—General Provisions

PRIOR VERSION	CHANGES	REVISED VERSION
<b>§484.1 Basis and scope</b>	Yes	<b>§484.1 Basis and scope</b>  Basis establishes the conditions that an HHA must meet in order to participate in the Medicare program based on statute.  Scope is the survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.  Includes interpretive guidelines.
<b>Definitions:</b>	Yes	<b>§484.2 Definitions: Adds the following terms used in the Appendix B</b>  Allowed practitioner; Branch office; Clinical note; Clinical nurse specialist; In advance; Nurse practitioner; Parent home health agency; Physician; physician assistant; Primary home health agency; Proprietary agency; Pseudo patient; Public agency; Quality indicator, Representative; Simulation; Subdivision; Summary report; Supervised practical training; Verbal orders.

## Subpart B—Patient Care

<b>§484.40 Condition of participation: Release of patient identifiable OASIS information</b>	No	<b>G350</b> <b>§484.40 Condition of participation: Release of patient identifiable OASIS information</b>
<b>§484.45 Condition of participation: Reporting OASIS information</b>	Yes	<b>G370-G386</b> <b>§484.45 Condition of participation: Reporting OASIS information</b>  Expands on the IGs to include reference to §484.55 which requires HHAs to use a standard core assessment data set, the OASIS. Recommends agencies keep copies of the validation reports for 12 months.  States that the <del>comprehensive assessment</del> and OASIS reporting regulations are not applicable to patients receiving personal care only services, regardless of pay or source.
<b>§484.50 Condition of participation: Patient rights</b>	Yes	<b>G406-G590</b> <b>§484.50 Condition of participation: Patient rights</b>  Includes IGs that HHAs must inform patients of their rights and protect and promote the exercise of these rights, e.g., by informing the patient how to exercise those rights.  The manner and degree of noncompliance identified in relation to the standard level tags for §484.50 may result in substantial noncompliance with this CoP, requiring citation at the condition level.  Includes survey procedures.
<b>§484.50(a) Standard: Notice of rights</b>  Includes terms for "legal representative" and "in advance "	Yes	<b>§484.50(a) Standard: Notice of rights</b>  Terms moved to the definition section.  Maintains existing IGs.  Includes survey procedures.
<b>§484.50(b) Standard: Exercise of rights</b>	No	<b>§484.50(b) Standard: Exercise of rights</b>
<b>§484.50(c) Standard: Rights of the patient</b>	Yes	<b>§484.50(c) Standard: Rights of the patient</b>  Includes survey procedures.
<b>§484.50(d) Standard: Transfer and discharge</b>	No	<b>§484.50(d) Standard: Transfer and discharge</b>

PRIOR VERSION	CHANGES	REVISED VERSION
<p><b>§484.50(e) Standard: Investigation of complaints</b></p>	<p>Yes</p>	<p><b>§484.50(e) Standard: Investigation of complaints</b></p> <p>Combined G tags 480-482 under G tag 478.</p> <p>Addresses requirements to follow state laws as well as federal laws.</p> <p>Includes survey procedures.</p>
<p><b>§484.50(f) Standard: Accessibility</b></p>	<p>No</p>	<p><b>§484.50(f) Standard: Accessibility</b></p>
<p><b>§484.55 Condition of participation: Comprehensive assessment of patients</b></p>	<p>Yes</p>	<p><b>G510-G550</b></p> <p><b>§484.55 Condition of participation: Comprehensive assessment of patients</b></p> <p>Describes the need for comprehensive assessment.</p> <p>Includes survey procedures.</p>
<p><b>§484.55(a) Standard: Initial assessment visit§</b></p>	<p>Yes</p>	<p><b>§484.55(a) Standard: Initial assessment visit</b></p> <p>References OASIS coding guidance for M0104 (definition of referral date).</p> <p>Includes guidance for a regulatory change that allows OTs to conduct the initial and comprehensive assessments in therapy only cases.</p>
<p><b>§484.55(b) Standard: Completion of the comprehensive assessment</b></p>	<p>Yes</p>	<p><b>§484.55(b) Standard: Completion of the comprehensive assessment</b></p> <p>Reiterates that the RN is to conduct the initial and comprehensive assessments when nursing is ordered.</p> <p>Includes survey procedures.</p>
<p><b>§484.55(c) Standard: Content of the comprehensive assessment</b></p> <p>In rehabilitation therapy only cases, the patient’s therapist must submit a list of patient medications, which the therapist must collect during the comprehensive assessment, to an HHA nurse for review. The HHA should contact the physician if indicated.</p>	<p>Yes</p>	<p><b>§484.55(c) Standard: Content of the comprehensive assessment</b></p> <p>Lifts the requirement for the RN to review the medication list in therapy cases.</p> <p>Includes survey procedures.</p>

PRIOR VERSION	CHANGES	REVISED VERSION
<p><b>§484.55(d) Standard: Update of the comprehensive assessment</b></p>	<p>Yes</p>	<p><b>§484.55(d) Standard: Update of the comprehensive assessment</b></p> <p>References OASIS guidance for two-day time frame to complete the discharge assessment.</p> <p>Reviews the goal of discharge planning and data and quality resources available on CMS' website.</p> <p>References §484.110(a)(6) for discharge and transfer summary requirements.</p>
<p><b>§ 484.58 Condition of participation: Discharge planning</b></p>	<p>Yes</p>	<p><b>G550-G556</b></p> <p><b>§484.58 Condition of participation: Discharge planning</b></p> <p>The manner and degree of noncompliance identified in relation to the standard level tags for §484.58 may result in substantial noncompliance with this CoP, requiring citation at the condition level.</p>
<p><b>§484.58(a) Standard: Discharge planning</b></p>	<p>Yes</p>	<p><b>§484.58(a) Standard: Discharge planning</b></p> <p>Defines the goal of discharge planning and data on quality and resource use measure.</p>
<p><b>§484.58(b) Standard: Discharge or transfer summary content</b></p>	<p>Yes</p>	<p><b>§484.58(b) Standard: Discharge or transfer summary content</b></p> <p>Refers to §484.110(a)(6) for discharge and transfer summary requirements.</p> <p>Separates the standard to comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner into its own tag.</p>
<p><b>§484.60 Condition of participation: Care planning, coordination of services, and quality of care</b></p>	<p>No</p>	<p><b>G570-G622</b></p> <p><b>§484.60 Condition of participation: Care planning, coordination of services, and quality of care</b></p>
<p><b>§484.60(a) Standard: Plan of care</b></p> <p>(i) "All pertinent diagnoses" means all known diagnoses.</p>	<p>Yes</p>	<p><b>§484.60(a) Standard: Plan of care</b></p> <p>Clarifies requirements for handling of missed visit.</p> <p>Removes the definition of pertinent dx as all "known diagnoses."</p> <p>Pertinent diagnoses include, but are not limited to, the chief reason the patient is receiving home care and the diagnosis most related to the current home health plan of care.</p> <p>Clarifies that required supplies and equipment are to be listed.</p> <p>Clarifies that the plan of care may include orders for treatment or services received from physicians other than the responsible physician.</p>

PRIOR VERSION	CHANGES	REVISED VERSION
<b>§484.60(b) Standard: Conformance with the physician or allowed practitioner orders</b>	No	<b>§484.60(b) Standard: Conformance with the physician or allowed practitioner orders</b>
<b>§484.60(c) Standard: Review and revision of the plan of care</b>	Yes	<b>§484.60(c) Standard: Review and revision of the plan of care</b> Includes survey procedures.
<b>§484.60(d) Standard: Coordination of Care</b>	Yes	<b>§484.60(d) Standard: Coordination of Care</b> Includes survey procedures.
<b>§484.60(e) Standard: Written information to the patient</b>	Yes	<b>§484.60(e) Standard: Written information to the patient</b> Includes survey procedures.
<b>§484.65 Condition of participation: Quality assessment and performance improvement (QAPI)</b>	Yes	<b>G640-G660</b> <b>§484.65 Condition of participation: Quality assessment and performance improvement (QAPI)</b>  The manner and degree of noncompliance identified in relation to the standard level tags for §484.65 may result in substantial noncompliance with this CoP, requiring citation at the condition level.
<b>§484.65(a) Standard: Program scope</b>	No	<b>§484.65(a) Standard: Program scope</b>
<b>§484.65(b) Standard: Program data</b>	Yes	<b>§484.65(b) Standard: Program data</b> Addresses new HHAs where limited data may be available.
<b>§484.65(c) Standard: Program activities</b>	Yes	<b>§484.65(c) Standard: Program activities</b>  Combines G Tags 646-652 into G642  Emphasizes tracking all adverse events for preventable interventions.  Includes survey procedures.
<b>§484.65(d) Standard: Performance improvement project</b>	Yes	<b>§484.65(d) Standard: Performance improvement project</b> Includes survey procedures.
<b>§484.65(e) Standard: Executive responsibilities</b>	Yes	<b>§484.65(e) Standard: Executive responsibilities</b>  Reinforces and elaborates on the responsibilities of the governing body.  Includes survey procedures.

<p><b>§484.70 Condition of participation: Infection prevention and control</b></p>	<p>Yes</p>	<p><b>G680-G686</b>  <b>§484.70 Condition of participation: Infection prevention and control</b></p> <p>Emphasizes the importance of a good IC program in the home health setting.</p> <p>The manner and degree of noncompliance identified in relation to the standard level tags for §484.70 may result in substantial noncompliance with this CoP, requiring citation at the condition level.</p>
<p><b>§484.70(a) Standard: Prevention</b></p>	<p>Yes</p>	<p><b>§484.70(a) Standard: Prevention</b></p> <p>Identifies sources for IC standards (CDC, APIC, etc.).</p> <p>Reiterates the 6 core practices for IC in healthcare and elaborates on several of the precautions.</p> <p>Includes survey procedures.</p>
<p><b>§484.70(b) Standard: Control</b></p>	<p>Yes</p>	<p><b>§484.70(b) Standard: Control</b></p> <p>While not required by the regulation, CMS suggests HHAs have a way to receive alerts from the CDC Health Alert Network or local public health network.</p>
<p><b>§484.70(c) Standard: Education</b></p>	<p>Yes</p>	<p><b>§484.70(c) Standard: Education</b></p> <p>The regulation does not specify the form or content of education regarding infection prevention and control. Must consider individualized POC.</p> <p>Includes survey procedures.</p>
<p><b>§484.75 Condition of participation: Skilled professional services</b></p>	<p>Yes</p>	<p><b>G700-G730</b>  <b>§484.75 Condition of participation: Skilled professional services</b></p> <p>The manner and degree of noncompliance identified in relation to the standard level tags for §484.75 may result in substantial noncompliance with this CoP, requiring citation at the condition level.</p>
<p><b>§484.75(a) Standard: Provision of services by skilled professionals</b></p>	<p>No</p>	<p><b>§484.75(a) Standard: Provision of services by skilled professionals</b></p>
<p><b>§484.75(b) Standard: Responsibilities of skilled professionals</b></p>	<p>Yes</p>	<p><b>§484.75(b) Standard: Responsibilities of skilled professionals</b></p> <p>Includes survey procedures.</p>

PRIOR VERSION	CHANGES	REVISED VERSION
<b>§484.75(c) Standard: Supervision of skilled professional assistants</b>	Yes	<p><b>§484.75(c) Standard: Supervision of skilled professional assistants</b></p> <p>References §484.115 for qualification of an RN.</p> <p>Added MSW has 1 year experience in healthcare.</p> <p>Includes survey procedures.</p>
<b>§484.80 Condition of participation: Home health aide services</b>	No	<p><b>G750-G828</b></p> <p><b>§484.80 Condition of participation: Home health aide services</b></p> <p>The manner and degree of noncompliance identified in relation to the standard level tags for §484.80 may result in substantial noncompliance with this CoP, requiring citation at the condition level.</p>
<b>§484.80(a) Standard: Home health aide qualifications</b>	Yes	<p><b>§484.80(a) Standard: Home health aide qualifications</b></p> <p>Adds IGs to clarify 24-month lapse and defines compensation (monetary).</p>
<b>§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training</b>	Yes	<p><b>§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training</b></p> <p>Clarifies that alternative formats for classroom training, such as online course material or internet based interactive formats are acceptable delivery methods for the classroom training but must provide an interactive component.</p> <p>Includes survey procedures.</p>
<b>§484.80(c) Standard: Competency evaluation</b>	Yes	<p><b>§484.80(c) Standard: Competency evaluation</b></p> <p>Defines pseudo patient and conditions for when a pseudo patient may be used.</p>
<b>§484.80(d) Standard: In-service training</b>	Yes	<p><b>§484.80(d) Standard: In-service training</b></p> <p>Adds that it is permissible for HHAs to use in-service education through another organization if it is under the supervision of an RN.</p> <p>Includes survey procedures.</p>
<b>§484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training</b>	Yes	<p><b>§484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training</b></p> <p>Includes IGs for qualifications of the RN instructor. Includes physicians as others that may help with training.</p>

PRIOR VERSION	CHANGES	REVISED VERSION
<p><b>§484.80(f) Standard: Eligible training and competency evaluation organizations</b></p>	<p>Yes</p>	<p><b>§484.80(f) Standard: Eligible training and competency evaluation organizations</b></p> <p>Combines G-Tag 784-796 into G-Tag 782.</p> <p>Reiterates exclusions for performing training and competency evals by the HHAs.</p> <p>Clarifies that if a HHA is precluded from performing training and competency evaluations, an outside contractor may use the HHA’s facility to train and evaluate the aides.</p>
<p><b>§484.80(g) Standard: Home health aide assignments and duties</b></p>	<p>Yes</p>	<p><b>§484.80(g) Standard: Home health aide assignments and duties</b></p> <p>Clarifies that when both nursing and therapy services are involved, either skilled professional may assign home health aides and develop written patient care instructions.</p> <p>Elaborates on the expectations for interdisciplinary team and emphasizes the role of home care aide as part of the team.</p>
<p><b>§484.80(h) Standard: Supervision of home health aides</b></p>	<p>Yes</p>	<p><b>§484.80(h) Standard: Supervision of home health aides</b></p> <p>Separates clauses and sentences in the regulation at §484.80(h)(1) (i) into two sections (A and B)</p> <p>Adds a new section outlining regulations that went into effect 1/1/22 that allows for two-way audio-video telecommunications technology.</p> <p>To be used, but not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.</p> <p>Eliminates guidance that the skilled nurse makes the supervisory visit when nursing and therapy is ordered.</p> <p>Adds new regulation effective 1/1/22 — That the registered nurse must make an onsite visit semi-annually to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.</p> <p>Combines G Tags 822-826 into G Tag 820.</p>
<p><b>§484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit</b></p>	<p>No</p>	<p><b>§484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit</b></p>

## Subpart C—Organizational Environment

<p><b>§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients</b></p>	Yes	<p><b>G848-G864</b>  <b>484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients</b></p> <p>Combines G Tags 852-858 into G Tag 850</p> <p>Refers to Appendix C of the CMS State Operations Manual for laboratory requirements.</p>
<p><b>§484.102 Condition of participation: Emergency preparedness</b></p>	Yes	<p><b>§484.102 Condition of participation: Emergency preparedness</b></p> <p>Refers to Appendix Z for regulatory text and IGs.</p> <p>HHAs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. For all applicable requirements and guidance for Emergency Preparedness, please refer to Appendix Z. We note that compliance with the emergency preparedness requirements is assessed in accordance with the survey protocol outlined within Appendix Z.</p>
<p><b>§484.105 Condition of participation: Organization and administration of services</b></p>	No	<p><b>G940-G988</b>  <b>§484.105 Condition of participation: Organization and administration of services.</b></p>
<p><b>§484.105(a) Standard: Governing body</b></p>	Yes	<p><b>§484.105(a) Standard: Governing body</b></p> <p>Defines components and responsibilities of the governing body.</p>
<p><b>§484.105(b)(1) Standard: Administrator</b></p> <p>Interpretive Guidelines.</p> <p>“Report to” means the administrator reports directly to the governing body with no intermediaries. “</p>	Yes	<p><b>§484.105(b)(1) Standard: Administrator</b></p> <p>Defines the responsibilities of the administrator, and that the administrator is appointed by and reports to the governing body.</p> <p>Eliminates the definition for the term “Report to.”</p> <p>Greater emphasis on “pre-designation” HHA staff should know and be able to verbalize upon interview who the pre-designated individual(s) is/are for this role.</p>
<p><b>§484.105(c) Standard: Clinical manager</b></p>	No	<p><b>§484.105(c) Standard: Clinical manager</b></p>
<p><b>§484.105(d) Standard: Parent-branch relationship</b></p>	Yes	<p><b>§484.105(d) Standard: Parent-branch relationship</b></p> <p>Includes survey procedures.</p>
<p><b>§484.105(e) Standard: Services under arrangement</b></p>	No	<p><b>§484.105(e) Standard: Services under arrangement</b></p>

PRIOR VERSION	CHANGES	REVISED VERSION
<b>§484.105(f) Standard: Services furnished</b>	Yes	<b>§484.105(f) Standard: Services furnished</b> Provides resources for accepted standards of practice.
<b>§484.105(g) Standard: Outpatient physical therapy or speech-language pathology services</b>	Yes	<b>§484.105(g) Standard: Outpatient physical therapy or speech-language pathology services</b> In general, this guidance is for situations where a patient would be coming to the premises of the HHA for outpatient therapy services.
<b>§484.105(h) Standard: Institutional planning</b>	No	<b>§484.105(h) Standard: Institutional planning</b>
<b>§484.110 Condition of participation: Clinical records</b>	Yes	<b>G1008-G1030</b> <b>§484.110 Condition of participation: Clinical records</b> The HHA must use the information contained in each medical record to assure that safe care is delivered to each HHA patient and ensure confidentiality.  The manner and degree of noncompliance identified in relation to the standard level tags for §484.110 may result in substantial noncompliance with this CoP, requiring citation at the condition level.
<b>§484.110(a) Standard: Contents of clinical record</b> The record must include:	No	<b>§484.110(a) Standard: Contents of clinical record.</b> The record must include:
<b>§484.110(b) Standard: Authentication</b>	No	<b>§484.110(b) Standard: Authentication</b>
<b>§484.110(c) Standard: Retention of records</b>	No	<b>§484.110(c) Standard: Retention of records</b>
<b>§484.110(d) Standard: Protection of records</b>	Yes	<b>§484.110(d) Standard: Protection of records</b> Reiterates the need to comply with Section 45 CFR Parts 160 and 164. HIPAA privacy and security rules.  Includes survey procedures.
<b>§484.110(e) Standard: Retrieval of clinical records</b>	No	<b>§484.110(e) Standard: Retrieval of clinical records</b>
<b>§484.115 Condition of participation: Personnel qualifications</b>	Yes	<b>G1050 – G1078</b> <b>§484.115 Condition of participation: Personnel qualifications</b> The manner and degree of noncompliance identified in relation to the standard level tags for §484.115 may result in substantial noncompliance with this CoP, requiring citation at the condition level.  No other changes to this CoP.

