



Center for Clinical Standards and Quality /Quality, Safety & Oversight Group

Ref: QSO-18-13-HHA

REVISED 01.16.18

DATE: January 12, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group (*formerly Survey & Certification Group*)

SUBJECT: Home Health Agency (HHA) Survey Protocol – State Operations Manual (SOM)
Appendix B Revised

****Revised Attachments A & B to Reflect Removal of Tags G670, G700, G848 and G940;
Addition of G956 and G984****

Memorandum Summary

This memorandum revises Appendix B of the SOM pursuant to new Conditions of Participation (CoPs) for HHA which are effective January 13, 2018:

- New Aspen tags for each condition and standard for the new CoPs are attached to this memorandum. These tags will be used by the surveyors to enter survey data into the system as of January 13, 2018.
- Revised Level I and Level II standards, based on the new CoPs, are attached to this memorandum. The surveyors must use Level I and II standards to conduct standard and partially extended HHA surveys per Appendix B of the SOM.
- The survey process within Appendix B of the SOM is revised to reduce pre-survey preparation time and refocus the use of Certification and Survey Provider Enhanced Reports (CASPER) reports in the HHA sample selection. The total number of patient clinical record reviews has been reduced.

Discussion

Revised HHA CoPs will be effective January 13, 2018. Pursuant to the new regulations, certain portions of the SOM Appendix B have been revised.

Attachment A of this memorandum forwards the new ASPEN tags assigned to each of the new HHA conditions and standards. These new ASPEN tags will be uploaded into the ASPEN system in preparation for use beginning on January 22, 2018. The Level I and level II standards for the new HHA CoPs have been identified (highlighted) for the convenience of the surveyors.

Attachment B of this memorandum is a table of the new Level I and Level II standards for the new HHA CoPs to be used during the standard and partially extended surveys as discussed in Appendix B of the SOM.

Selected sections of the HHA survey process have also been revised and will be effective with all surveys conducted upon receipt of this memorandum. These changes replace the current, corresponding sections within Appendix B of the SOM. The changes are:

Task 1 - Pre-Survey (Offsite) Preparation

The offsite preparation task has been refocused to optimize surveyor time in planning for the HHA survey and to shift the focus of the offsite review to potentially avoidable events. The number of CASPER HHA reports that are to be reviewed prior to the HHA survey is reduced from six to three reports.

The three CASPER reports that surveyors will continue to review during Task 1 are:

1. Risk Adjusted Potentially Avoidable Event Report (12 months);
2. Potentially Avoidable Event Report: Patient Listing (12 months);
3. Agency Patient Related- Characteristics Report (12 months).

1. Risk Adjusted Potentially Avoidable Event Report

Surveyors will continue to utilize the Risk Adjusted Potentially Avoidable Event Report to identify potential areas of concern for the survey. Review the report to identify all potentially avoidable events. It is no longer required that the surveyor analyze this report for statistical significance or to determine if the provider exceeded twice the national reference value for a particular concern. All incidents contained within the report time period should be used as the universe, in conjunction with the *Potentially Avoidable Event: Patient Listing Report*, from which the closed record sample for the survey is selected. The closed record sample is selected during the pre-survey preparation. If the reports do not contain a sufficient number of events, the sample may be augmented onsite.

2. Potentially Avoidable Event: Patient Listing Report

This report is a companion to the above *Potentially Avoidable Event Report* and provides the names of the patients who experienced the events noted in that report. Patients listed under multiple areas in the above report should be selected as a priority. If an insufficient number of patients are listed in the *Potentially Avoidable Event Report* to meet the number of closed records required for the survey sample, additional records may be added to the sample from the list of patients discharged from the agency for the 6 months prior to the survey.

3. Agency Patient-Related Characteristics Report

Surveyors will continue to review this report, which compiles several OASIS data elements into one report that provides a high-level overview of the HHA patient demographics, home care diagnoses, and agency statistics. Surveyors should identify potential focus areas of concern where the agency's indicators exceed the national reference in the areas of Acute Conditions, Patient Diagnostic Information, and Home Care Diagnoses. Select patients for review and home visits during the survey who be associated with these areas of concern.

Task 3: Information Gathering

The minimum clinical record/sample size for HHA surveys has been revised as follows in Table

1. More clinical records may be reviewed and more home visits conducted as deemed necessary

to adequately assess compliance with the CoPs when deficient practice has been identified during the survey.

Table 1. HHA Survey Sample—Revised

Number of unduplicated skilled care admissions for the 12 months prior to the survey	Active Patient Sample: Record Review Only (No Home Visit)	Active Patient Sample: Record Review with Home Visit	Discharged Patients: Closed Record Review	Total Survey Sample
Less than 300	2	3	2	7
301 - 500	3	4	3	10
501 - 700	4	5	4	<i>13</i>
701 or more	5	7	5	<i>17</i>

Contact: Questions concerning this memorandum may be addressed to: HHA.SCG@cms.hhs.gov and David Escobedo at david.escobedo@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment(s):

Attachment A- Revised ASPEN Tags with Level I and Level II Tags Highlighted

Attachment B-Revisions to the Level I and Level II HHA Standard/Partially Extended Survey Standards

cc: Survey and Certification Regional Office Management

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

Regulatory Reference	G Tag	All HHA Tags Blue Shading = Level 1 Green Shading = Level 2
484.40	G350	Condition: Release of patient identifiable OASIS info.
484.45	G370	Condition: Reporting OASIS information
484.45(a)	G372	Standard: Encoding and transmitting OASIS
484.45(b)	G374	Standard: Accuracy of encoded OASIS data
484.45(c)	G376	Standard: Transmittal of OASIS data
484.45(c)(1)	G378	OASIS data transmission format
484.45(c)(2)	G380	Successfully transmit test data
484.45(c)(3)	G382	Transmit data using compliant software
484.45(c)(4)	G384	Transmit data that includes branch identifier
484.45(d)	G386	Standard: Data Format
484.50	G406	Condition: Patient rights
484.50(a)	G408	Standard: Notice of rights
484.50(a)(1)	G410	Information to patient
484.50(a)(1)(i)	G412	Written notice of patient's rights
484.50(a)(1)(ii)	G414	HHA administrator contact information
484.50(a)(1)(iii)	G416	OASIS privacy notice
484.50(a)(2)	G418	Patient's or legal representative's signature
484.50(a)(3)	G420	Verbal notice of rights and responsibilities
484.50(a)(4)	G422	Written notice within 4 business days
484.50(b)	G424	Standard: Exercise of rights
484.50(c)	G426	Standard: Rights of the patient
484.50(c)(1)	G428	Property and person treated with respect
484.50(c)(2)	G430	Be free from abuse
484.50(c)(3)	G432	Make complaints to the HHA
484.50(c)(4)	G434	Participate in care
484.50(c)(5)	G436	Receive all services in plan of care
484.50(c)(6)	G438	Have a confidential clinical record
484.50(c)(7)	G440	Payment from federally funded programs
484.50(c)(8)	G442	Written notice for non-covered care
484.50(c)(9)	G444	State toll free HH telephone hotline
484.50(c)(10)	G446	Contact info Federal/State-funded entities
484.50(c)(11)	G448	Freedom from discrimination or reprisal
484.50(c)(12)	G450	Access to auxiliary aids and language service
484.50(d)	G452	Standard: Transfer and discharge
484.50(d)(1)	G454	HHA can no longer meet the patient's needs
484.50(d)(2)	G456	Patient/payer will no longer pay for services
484.50(d)(3)	G458	Outcomes/goals have been achieved
484.50(d)(4)	G460	Patient refuses services
484.50(d)(5)	G462	Before discharge for cause HHA must:
484.50(d)(5)(i)	G464	Advise the patient of discharge for cause
484.50(d)(5)(ii)	G466	Make efforts to resolve the problem(s)
484.50(d)(5)(iii)	G468	Provide contact info other services
484.50(d)(5)(iv)	G470	Document efforts to resolve problems
484.50(d)(6)	G472	Death of patient

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

484.50(d)(7)	G474	HHA ceases to operate
484.50(e)(1)	G476	Standard: Investigation of complaints
484.50(e)(1)(i)	G478	Investigate complaints made by patient
484.50(e)(1)(i)(A)	G480	Treatment or care
484.50(e)(1)(i)(B)	G482	Mistreatment, neglect or abuse
484.50(e)(1)(ii)	G484	Document complaint and resolution
484.50(e)(1)(iii)	G486	Protect patient during investigation
484.50(e)(2)	G488	Immediate reporting of abuse by all staff
484.50(f)(1,2)	G490	Standard: Accessibility
484.55	G510	Condition: Comprehensive Assessment of Patients
484.55(a)	G512	Standard: Initial assessment visit.
484.55(a)(1)	G514	RN performs assessment
484.55(a)(2)	G516	Skilled professional performs assessment
484.55(b)	G518	Standard: Completion of the comprehensive assessment
484.55(b)(1)	G520	5 calendar days after start of care
484.55(b)(2)	G522	Eligibility for Medicare home health benefit
484.55(b)(3)	G524	Therapy services determine eligibility
484.55(c)	G526	Standard: Content of the comprehensive assessment
484.55(c)(1)	G528	Health, psychosocial, functional, cognition
484.55(c)(2)	G530	Strengths, goals, and care preferences
484.55(c)(3)	G532	Continuing need for home care
484.55(c)(4)	G534	Patient's needs
484.55(c)(5)	G536	A review of all current medications
484.55(c)(6)	G538	Primary caregiver(s), if any
484.55(c)(7)	G540	The patient's representative (if any);
484.55(c)(8)	G542	Incorporate OASIS items
484.55(d)	G544	Standard: Update of the comprehensive assessment
484.55(d)(1)	G546	Last 5 days of every 60 days unless:
484.55(d)(2)	G548	Within 48 hours of the patient's return
484.55(d)(3)	G550	At discharge
484.60	G570	Condition: Care planning, coordination, quality of care
484.60(a)(1)	G572	Standard: Plan of care
484.60(a)(2)	G574	Plan of care must include the following
484.60(a)(3)	G576	All orders recorded in plan of care
484.60(b)	G578	Standard: Conformance with physician orders
484.60(b)(1)	G580	Only as ordered by a physician
484.60(b)(2)	G582	Influenza and pneumococcal vaccines
484.60(b)(3)(4)	G584	Verbal orders
484.60(c)	G586	Standard: Review and revision of the plan of care
484.60(c)(1)	G588	Reviewed, revised by physician every 60 days
484.60(c)(1)	G590	Promptly alert relevant physician of changes
484.60(c)(2)	G592	Revised plan of care
484.60(c)(3)	G594	Plan of care revisions must be communicated
484.60(c)(3)(i)	G596	Revisions communicated to patient and MDs
484.60(c)(3)(ii)	G598	Discharge plans communication
484.60(d)	G600	Standard: Coordination of Care

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

484.60(d)(1)	G602	Communication with all physicians
484.60(d)(2)	G604	Integrate all orders
484.60(d)(3)	G606	Integrate all services
484.60(d)(4)	G608	Coordinate care delivery
484.60(d)(5)	G610	Patients receive education and training
484.60(e)	G612	Standard: Written instructions to patient include:
484.60(e)(1)	G614	Visit schedule
484.60(e)(2)	G616	Patient medication schedule/instructions
484.60(e)(3)	G618	Treatments and therapy services
484.60(e)(4)	G620	Other pertinent instructions
484.60(e)(5)	G622	Name/contact information of clinical manager
484.65	G640	Condition: Quality assessment/performance improvement
484.65(a)(1),(2)	G642	Standard: Program scope
484.65(b)(1),(2),(3)	G644	Standard: Program data
484.65(c)	G646	Standard: Program activities
484.65(c)(1)(i)	G648	High risk, high volume, or problem-prone area
484.65(c)(1)(ii)	G650	Incidence, prevalence, severity of problems
484.65(c)(1)(iii)	G652	Activities lead to an immediate correction
484.65(c)(2)	G654	Standard: Track adverse patient events
484.65(c)(3)	G656	Improvements are sustained
484.65(d)(1)(2)	G658	Standard: Performance improvement projects
484.65(e)(1)(2)(3)(4)	G660	Standard: Executive responsibilities for QAPI
484.70	G680	Condition: Infection prevention and control
484.70(a)	G682	Standard: Prevention
484.70(b)(1)(2)	G684	Standard: Infection control
484.70(c)	G686	Standard: Infection control education
484.75	G700	Condition: Skilled professional services
484.75(a)	G702	Standard: Services by skilled professionals
484.75(b)	G704	Standard: Responsibilities of skilled professionals
484.75(b)(1)	G706	Interdisciplinary assessment of the patient
484.75(b)(2)	G708	Development and evaluation of plan of care
484.75(b)(3)	G710	Provide services in the plan of care
484.75(b)(4)	G712	Patient, caregiver, and family counseling
484.75(b)(5)	G714	Patient and caregiver education
484.75(b)(6)	G716	Preparing clinical notes
484.75(b)(7)	G718	Communication with physicians
484.75(b)(8)	G720	Participate in the HHA's QAPI program;
484.75(b)(9)	G722	Participate in HHA-sponsored in-service
484.75(c)	G724	Standard: Supervise skilled professional assistants
484.75(c)(1)	G726	Nursing services supervised by RN
484.75(c)(2)	G728	Rehab services supervised by PT, OT
484.75(c)(3)	G730	Medical social services supervised by MSW
484.80	G750	Condition: Home health aide services
484.80(a)	G752	Standard: Home health aide qualifications
484.80(a)(1)	G754	A qualified HH aide successfully completed:
484.80(a)(2)	G756	24 consecutive months paid service

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

484.80(b)	G758	Standard: Content and duration of training
484.80(b)(1)	G760	Classroom and supervised practical training
484.80(b)(2)	G762	Minimum hours of training
484.80(b)(3)	G764	HH aide training program topics
484.80(b)(4)	G766	HHA maintains documentation of training
484.80(c)(1)(2)(3)	G768	Standard: Competency evaluation
484.80(c)(4)	G770	Unsatisfactory competency evaluation
484.80(c)(5)	G772	Documentation of competency evaluation
484.80(d)	G774	Standard: 12 hours inservice every 12 months
484.80(d)(1)	G776	Inservice training supervised by RN
484.80(d)(2)	G778	Documentation of inservice training
484.80(e)	G780	Standard: Instructor qualifications
484.80(f)	G782	Standard: Eligible training/competency evaluation orgs.
484.80(f)(1)	G784	Noncompliance with training requirements
484.80(f)(2)	G786	Unqualified HH aide providing services
484.80(f)(3)	G788	Org. had partial/extended survey
484.80(f)(4)	G790	Assessed a civil monetary penalty = \$5,000
484.80(f)(5)	G792	Deficiencies that endangered health/safety
484.80(f)(6)	G794	Medicare payments suspended
484.80(f)(7)	G796	Violations of federal or state law:
484.80(g)(1)	G798	Standard: Home health aide assignments and duties
484.80(g)(2)	G800	Services provided by HH aide
484.80(g)(3)	G802	Duties of a HH aide
484.80(g)(4)	G804	Aides are members of interdisciplinary team
484.80(h)	G806	Standard: Supervision of home health aides
484.80(h)(1)(i)	G808	Onsite supervisory visit every 14 days
484.80(h)(1)(ii)	G810	If concern identified, direct observation
484.80(h)(1)(iii)	G812	Direct observation every 12 months
484.80(h)(2)	G814	Non-skilled direct observation every 60 days
484.80(h)(3)	G816	Competency eval. if deficiency identified
484.80(h)(4)	G818	HH aide supervision elements
484.80(h)(5)	G820	HH aide services under arrangement
484.80(h)(5)(i)	G822	Ensuring the overall quality of care provided
484.80(h)(5)(ii)	G824	Supervising HH aide services
484.80(h)(5)(iii)	G826	Ensure training/competency requirements
484.80(i)	G828	Standard: Medicaid personal care aide-only services
484.100	G848	Condition: Compliance with Federal, State, Local Law
484.100(a)	G850	Standard: Disclosure of ownership and management info.
484.100(a)	G852	Standard: Information to the state survey agency
484.100(a)(1)	G854	All persons with ownership interest
484.100(a)(2)	G856	Officer, a director, agent, managing employee
484.100(a)(3)	G858	Responsible for the management of the HHA
484.100(b)	G860	Standard: Licensing
484.100(c)(1)	G862	Standard: Laboratory services/CLIA waivers
484.100(c)(2)	G864	Referral laboratory must be certified
484.102	E-0001	Condition: Emergency preparedness

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

<i>Refer to Emergency Preparedness E-Tags and Appendix Z</i>		
484.102(a)	E-0004	Standard: Emergency plan
484.102(a)(1)(2)	E-0006	Risk assessment
484.102(a)(3)	E-0007	Address patient population
484.102(a)(4)	E-0009	Process for cooperation and collaboration
484.102(b)	E-0013	Standard: Policies and procedures
484.102(b)(1)	E-0017	Plans for HHA's patients in plan of care
484.102(b)(2)	E-0019	Procedures to inform State/Local officials
484.102(b)(3)	E-0021	Procedures to follow up with staff/pts.
484.102(b)(4)	E-0023	Secures and maintains availability of records
484.102(b)(5)	E-0024	Use of volunteers in an emergency
484.102(c)	E-0029	Standard: Communication plan
484.102(c)(1)	E-0030	Names and contact information
484.102(c)(2)	E-0031	Contact info for emergency officials
484.102(c)(3)	E-0032	Primary and alternate communication info
484.102(c)(4)(5)	E-0033	Continuity of care
484.102(c)(6)	E-0034	Providing information about HHA
484.102(d)	E-0036	Standard: Training and testing
484.102(d)(1)	E-0037	Standard: EP Training Program
484.102(d)(2)	E-0039	EP Testing Program
484.102(e)	E-0042	Standard: Integrated healthcare systems
484.105	G940	<i>Condition: Organization and administration of services</i>
484.105(a)	G942	Standard: Governing body
484.105(b)(1)	G944	Standard: Administrator must:
484.105(b)(1)(i)	G946	Administrator appointed by governing body
484.105(b)(1)(ii)	G948	Responsible for all day-to-day operations
484.105(b)(1)(iii)	G950	Ensure clinical manager is available
484.105(b)(1)(iv)	G952	Ensure that HHA employs qualified personnel
484.105(b)(2)	G954	Ensures qualified pre-designated person
484.105(b)(3)	G956	Available during all operating hours
484.105(c)	G958	Standard: Clinical manager
484.105(c)(1)	G960	Make patient and personnel assignments,
484.105(c)(2)	G962	Coordinate patient care
484.105(c)(3)	G964	Coordinate referrals;
484.105(c)(4)	G966	Assure patient needs are continually assessed
484.105(c)(5)	G968	Assure implementation of plan of care
484.105(d)	G970	Standard: Parent-branch relationship
484.105(d)(1)	G972	Report all branch locations to SA
484.105(d)(2)	G974	Direct support and administrative control
484.105(e)(1)	G976	Standard: Services under arrangement
484.105(e)(2)	G978	Must have a written agreement
484.105(e)(3)	G980	Primary HHA is responsible for patient care
484.105(f)	G982	Standard: Skilled services furnished
484.105(f)(2)	G984	In accordance with current clinical practice
484.105(g)	G986	Standard: Outpatient therapy services
484.105(h)	G988	Standard: Institutional planning

Attachment A: All HHA Tags with Level 1 and Level 2 Tags Highlighted

484.110	G1008	<i>Condition: Clinical records</i>
484.110(a)	G1010	Standard: Contents of clinical record
484.110(a)(1)	G1012	Required items in clinical record
484.110(a)(2)	G1014	Interventions and patient response
484.110(a)(3)	G1016	Goals in the patient's plans of care
484.110(a)(4)	G1018	Contact information for the patient
484.110(a)(5)	G1020	Contact info for primary care practitioner
484.110(a)(6)	G1022	Discharge and transfer summaries
484.110(b)	G1024	Standard: Authentication
484.110(c)(1)(2)	G1026	Standard: Retention of records
484.110(d)	G1028	Standard: Protection of records
484.110(e)	G1030	Standard: Retrieval of records
484.115	G1050	<i>Condition: Personnel qualifications</i>
484.115(a)	G1052	Standard: Administrator
484.115(b)	G1054	Standard: Audiologist
484.115(c)	G1056	Clinical Manager
484.115(d)	G1058	Standard: Home Health Aide
484.115(e)	G1060	Standard: Licensed Practical (Vocational) Nurse
484.115(f)	G1062	Standard: Occupational Therapist
484.115(g)	G1064	Standard: Occupational Therapy Assistant
484.115(h)	G1066	Standard: Physical Therapist
484.115(i)	G1068	Standard: Physical Therapist Assistant
484.115(j)	G1070	Standard: Physician
484.115(k)	G1072	Standard: Registered Nurse
484.115(l)	G1074	Standard: Social Work Assistant
484.115(m)	G1076	Standard: Social Worker
484.115(n)	G1078	Standard: Speech-Language Pathologist

Attachment B: Revisions to the Level 1 and Level 2 HHA Standard Survey Tags for the updated Conditions of Participation (revised 1-16-18)

Updates to the Level 1 and Level 2 Tags for Standard HHA Survey

The Level 1 and 2 tags correspond directly to the prior regulations to the extent possible, except where the regulatory requirements are broken out into different standards. During the standard survey, the surveyor reviews the HHA's compliance with a select number of regulations (standards) most related to high-quality patient care and address 8 of the 14 CoPs.

Table 1 lists the tags according to Condition; Table 2 contains the regulatory requirements associated with the tags. Table 3 suggests associated conditions that may be considered for further investigation when a condition of participation is cited in the 8 CoPs for the Standard HHA Survey.

Table 1. Level 1 and Level 2 Standards to determine compliance during a Standard Survey (Effective January 13, 2018)

CONDITION OF PARTICIPATION	Level 1 Standards (Priority Standards for a Standard Survey)	Level 2 (Primary Standards for a Partial Extended Survey)
§484.50 Patient Rights	G434, G476, G478, G480, G482, G484, G486, G488	G438
§484.55 Comprehensive Assessment Of Patients	G512, G514, G518, G520, G522, G524, G536, G544, G548	G546, G550
§484.60 Care planning, coordination of services, and quality of care. <i>(Removed G670 from Level 1)</i>	G572, G574, G578, G580, G582	G586, G588, G590
§484.75 Skilled Professional Services <i>(Removed G700 from Level 1)</i>	G704, G706, G708, G710, G712, G714, G716, G718	G724, G726, G728, G730
§484.80 Home Health Aide Services	G798, G808	G768, G774, G800, G802, G814, G820
§484.100 Compliance With Federal, State, And Local Laws and Regs. <i>(Removed G848 from Level 1)</i>	n/a	G860
§484.105 Organization and Administration of Services <i>(Added G984 to Level 1 and G956 to Level 2)</i>	G944, G946, G948, G950, G984	G954, G956, G958, G960, G962, G964, G966, G968

Attachment B: Revisions to the Level 1 and Level 2 HHA Standard Survey Tags for the updated Conditions of Participation (revised 1-16-18)

CONDITION OF PARTICIPATION	Level 1 Standards (Priority Standards for a Standard Survey)	Level 2 (Primary Standards for a Partial Extended Survey)
§484.110 Clinical Records.	G1010, G1012, G1014, G1016	G1028

Table 2. Level 1 and Level 2 Tags Regulatory Requirements

Level 1 and Level 2 Tags for HHA Standard Survey, Revised for New Conditions of Participation	
§484.50 Patient Rights	
Patient Rights Level 1 Tags	
G434 L1	§484.50(c)(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to-- (i) Completion of all assessments; (ii) The care to be furnished, based on the comprehensive assessment; (iii) Establishing and revising the plan of care; (iv) The disciplines that will furnish the care; (v) The frequency of visits; (vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits; (vii) Any factors that could impact treatment effectiveness; and (viii) Any changes in the care to be furnished.
G476 L1	§484.50(e) Standard: Investigation of complaints §484.50(e)(1) The HHA must—
G478 L1	§484.50(e)(1)(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:
G480 L1	§484.50(e)(1)(i)(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and
G482 L1	§484.50(e)(1)(i)(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.
G484 L1	§484.50(e)(1)(ii) Document both the existence of the complaint and the resolution of the complaint; and

Attachment B: Revisions to the Level 1 and Level 2 HHA Standard Survey Tags for the updated Conditions of Participation (revised 1-16-18)

G486 L1	§484.50(e)(1)(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.
G488 L1	§484.50(e)(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.
Patient Rights Level 2 Tags	
G438 L2	§484.50(c)(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.
§484.55 Comprehensive assessment of patients	
Comprehensive Assessment Level 1 Tags	
G512 L1	§484.55(a) Standard: Initial assessment visit
G514 L1	§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.
G518 L1	§484.55(b) Standard: Completion of the comprehensive assessment.
G520 L1	§484.55(b)(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.
G522 L1	§484.55(b)(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.
G524 L1	§484.55(b)(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility

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G536 L1	§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.
G544 L1	§484.55(d) Standard: Update of the comprehensive assessment. 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—
G548 L1	§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;
Comprehensive Assessment Level 2 Tags	
G546 L2	§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.
G550 L2	§484.55(d)(3) At discharge.
§484.60 Care planning, coordination of services, and quality of care	
Care planning, coordination of services, and quality of care Level 1 Tags	
G572 L1	§484.60(a) Standard: Plan of care. §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.
G574 L1	§484.60(a)(2) The individualized plan of care must include the following: (i) All pertinent diagnoses; (ii) The patient's mental, psychosocial, and cognitive status; (iii) The types of services, supplies, and equipment required; (iv) The frequency and duration of visits to be made; (v) Prognosis; (vi) Rehabilitation potential; (vii) Functional limitations; (viii) Activities permitted; (ix) Nutritional requirements;

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	<p>(x) All medications and treatments;</p> <p>(xi) Safety measures to protect against injury;</p> <p>(xii) 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.</p> <p>(xiii) Patient and caregiver education and training to facilitate timely discharge;</p> <p>(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;</p> <p>(xv) Information related to any advanced directives; and</p> <p>(xvi) Any additional items the HHA or physician may choose to include.</p>
G578 L1	§484.60(b) Standard: Conformance with physician orders.
G580 L1	§484.60(b)(1) Drugs, services, and treatments are administered only as ordered by a physician.
G582 L1	§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 contraindications.
Care planning, coordination of services, and quality of care Level 2 Tags	
G586 L2	§484.60(c) Standard: Review and revision of the plan of care.
G588 L2	§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....
G590 L2	§484.60(c)(1)...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.
§484.75 Skilled professional services	
Skilled professional services Level 1 Tags	
G704 L1	§484.75(b) Standard: Responsibilities of skilled professionals Skilled professionals must assume responsibility for, but not be restricted to, the following:
G706 L1	§484.75(b)(1) Ongoing interdisciplinary assessment of the patient;
G708 L1	§484.75(b) 2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);

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G710 L1	§484.75(b)(3) Providing services that are ordered by the physician as indicated in the plan of care;
G712 L1	§484.75(b)(4) Patient, caregiver, and family counseling;
G714 L1	§484.75(b)(5) Patient and caregiver education;
G716 L1	§484.75(b)(6) Preparing clinical notes;
G718 L1	§484.75(b)(7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;
Skilled professional services Level 2 Tags	
G724 L2	§484.75(c) Standard: Supervision of skilled professional assistants.
G726 L2	§484.75(c)(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).
G728 L2	§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(f) or (h), respectively.
G730 L2	§484.75(c)(3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).
§484.80 Condition of participation: Home health aide services	
Home health aide services Level 1 Tags	
G798 L1	§484.80(g) Standard: Home health aide assignments and duties §484.80(g)(1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).
G808 L1	§484.80(h)(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 who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in §484.80(g), 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.
Home health aide services Level 2 Tags	
G768	§484.80(c) Standard: Competency evaluation.

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L2	<p>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.</p> <p>§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), (iii), (ix), (x), and (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.</p> <p>§484.80(c)(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.</p> <p>§484.80(c)(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.</p>
G774 L2	<p>§484.80(d) Standard: In-service training.</p> <p>A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.</p>
G800 L2	<p>§484.80(g) (2) A home health aide provides services that are:</p> <ul style="list-style-type: none"> (i) Ordered by the physician; (ii) Included in the plan of care; (iii) Permitted to be performed under state law; and (iv) Consistent with the home health aide training.
G802 L2	<p>§484.80(g)(3) The duties of a home health aide include:</p> <ul style="list-style-type: none"> (i) The provision of hands-on personal care; (ii) The performance of simple procedures as an extension of therapy or nursing services; (iii) Assistance in ambulation or exercises; and (iv) Assistance in administering medications ordinarily self-administered.
G814 L2	<p>§484.80(h)(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.</p>
G820 L2	<p>§484.80(h)(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:</p> <ul style="list-style-type: none"> (i) Ensuring the overall quality of care provided by an aide; (ii) Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and (iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

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§484.100 Compliance with Federal, State, and local laws and regulations	
Compliance with Federal, State, and local laws and regulations related to the health and safety of patients Level 2 Tag	
G860 L2	§484.100(b) Standard: Licensing The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.
§484.105 Organization and administration of services.	
Organization and administration of services Level 1 Tags	
G944 L1	§484.105 (b) Standard: Administrator. §484.105(b)(1) The administrator must:
G946 L1	§484.105(b)(1)(i) Be appointed by and report to the governing body;
G948 L1	§484.105(b)(1)(ii) Be responsible for all day-to-day operations of the HHA;
G950 L1	§484.105(b)(1)(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;
G984 L1	§484.105(f)(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.
Organization and administration of services Level 2 Tags	
G954 L2	§484.105(b)(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.
G956 L2	§484.105(b)(3) The administrator or a pre-designated person is available during all operating hours.
G958 L2	§484.105(c) Standard: Clinical manager One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following--
G960 L2	§484.105(c)(1) Making patient and personnel assignments,
G962 L2	§484.105(c)(2) Coordinating patient care,

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G964 L2	§484.105(c)(3) Coordinating referrals,
G966 L2	§484.105(c) (4) Assuring that patient needs are continually assessed, and
G968 L2	§484.105(c)(5) Assuring the development, implementation, and updates of the individualized plan of care.
§484.110 Clinical records.	
Clinical Records Level 1 Tags	
G1010 L1	§484.110 (a) Standard: Contents of clinical record. The record must include:
G1012 L1	§484.110(a)(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders;
G1014 L1	§484.110(a)(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;
G1016 L1	§484.110(a)(3) Goals in the patient's plans of care and the patient's progress toward achieving them;
Clinical Records Level 2 Tag	
G1028 L2	§484.110(d) Standard: Protection of records. The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 and 164.

Table 3 suggests the related CoPs that may be considered for further investigation when indicated by the findings when a CoP is out of compliance. A CoP may be considered out of compliance for one or more deficiencies and cited at the condition-level, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious finding that adversely affects, or has the potential to adversely affect, patient outcomes. Surveyors are to use their professional judgment in their assessment of an HHA's compliance with the CoPs.

**Table 3: Related CoPs Associated with the Eight Condition Level 1 and 2 Tags
Noncompliance**

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Condition of participation out of Compliance	Related Conditions for Further Investigation
§484.50 Patient Rights	CoP 484.60: Care planning, Coordination of Services, and Quality of Care CoP 484.75: Skilled Professional Services CoP 484.100: Compliance with Federal, State & Local Laws CoP 484.105: Organization and Administration of Services
§484.55 Comprehensive Assessment Of Patients	CoP 484.60 Care planning, Coordination of Services, and Quality of Care CoP 484.65 Quality assessment and performance improvement CoP 484.75 Skilled Professional Services CoP 484.105 Organization and Administration of Services CoP 484.70 Infection Prevention and Control
§484.60 Care planning, coordination of services, and quality of care.	CoP 484.55: Comprehensive Assessment of Patients CoP 484.65 Quality assessment and performance improvement CoP 484.75: Skilled Professional Services CoP 484.80 Home Health Aide Services CoP 484.105 Organization, Services and Administration CoP 484.110 Clinical Records
§484.75 Skilled Professional Services	CoP 484.55 Comprehensive Assessment of Patients CoP 484.60 Care planning, Coordination of Services, and Quality of Care CoP 484.65 Quality assessment and performance improvement CoP 484.70 Infection Prevention and Control CoP 484.80: Home Health Aide Services CoP 484.100 Compliance with Fed. State, & local laws and regulations related to health and safety of pts. CoP 484.105 Organization, Services and Administration CoP 484.110 Clinical Records
§484.80 Home Health Aide Services	CoP 484.50 Patient Rights CoP 484.55: Comprehensive Assessment of Patients CoP 484.60 Care planning, Coordination of Services, and Quality of Care CoP 484.70 Infection Prevention and Control CoP 484.75: Skilled Professional Services CoP 484.100 Compliance with Fed. State, & local laws and regulations related to health and safety of pts. CoP 484.105 Organization, Services and Administration CoP 484.48: Clinical Records

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Condition of participation out of Compliance	Related Conditions for Further Investigation
§484.105 Organization and Administration of Services	CoP 484.50 Patient Rights CoP 484.55 Comprehensive Assessment of Patients CoP 484.60 Care planning, Coordination of Services, and Quality of Care CoP 484.65 Quality assessment and performance improvement CoP 484.70 Infection Prevention and Control CoP 484.75: Skilled Professional Services CoP 484.100 Compliance with Fed. State, & local laws and regulations related to health and safety of pts. CoP 484.110 Clinical Records
§484.110 Clinical Records.	CoP 484.45: Reporting OASIS Information CoP 484.55: Comprehensive Assessment of Patients CoP 484.60 Care planning, Coordination of Services, and Quality of Care CoP 484.75: Skilled Professional Services CoP 484.100 Compliance with Fed. State, & local laws and regulations related to health and safety of pts. CoP 484.105 Organization, Services and Administration