

DEPARTMENT: Clinical Operations Group – Regulatory and Accreditation Services	POLICY DESCRIPTION: Regulatory Compliance Notification
PAGE: 1 of 3	REPLACES POLICY DATED: 5/14/99, 7/21/99, 9/30/03, 9/1/07, 6/1/09, 5/1/15, 8/1/15, 9/1/18, 7/1/20
EFFECTIVE DATE: January 1, 2022	REFERENCE NUMBER: COG.RAS.001 (formerly QM.001, CSG.QS.001 & CSG.RAS.001)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated facilities including, but not limited to, hospitals, ambulatory surgery centers, home health agencies, hospice agencies, outpatient therapy agencies, physician practices, outpatient imaging centers, urgent care centers, and all Corporate Departments, Groups, Divisions, and Regional office/leadership. Specifically, the following departments:

- Administration
- Ethics and Compliance
- Quality Management

PURPOSE: To ensure that each Company-affiliated facility and subsidiary provides immediate notification to Corporate, Division, and Regional office/leadership:

- of any surveys by any third party agency for any reason at their facility;
- upon receipt of any request for copies of patient or facility records for use in an investigation of an alleged compliance violation;
- upon receipt of written communication from the facility's Quality Improvement Organization (QIO) or other health care survey or enforcement agency pertaining to a formal project that will involve aggregate reporting of data or information to the QIO or requesting agency; and
- upon identification by the facility of the obligation to notify a regulatory/accrediting body of an adverse event or violation of a state/federal regulation via self-report communication to the applicable body.

POLICY:

1. All Company-affiliated facilities must provide immediate notification to Corporate Regulatory and Accreditation Services and to their Division Vice President for Quality/Division Quality and Risk Manager for Ambulatory Surgery Centers (ASCs)/Division Quality Manager for Physician Services Group (PSG) when the following occur:
 - any survey visits by a third party agency;
 - upon receipt of any request for copies of patient or business records for use in the investigation of an alleged compliance violation by a third party agency;
 - upon receipt of communication from the facility's QIO or other health care survey or enforcement agency pertaining to a formal project that will involve aggregate reporting of data or information to the QIO or requesting agency; and
 - upon identification by the facility of the obligation to notify a regulatory/accrediting body of an adverse event or violation of a state/federal regulation via self-report communication to the applicable body.

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2. Corporate Regulatory and Accreditation Services will ensure that other Corporate, Division, and Regional office/leadership are notified of survey visits or events that relate to the their respective areas of responsibility.

PROCEDURE:

Facility Responsibility

1. Immediately upon the arrival of any survey team at the facility for any reason, the Chief Executive Officer/Administrator or their designee must notify the appropriate Division or Regional office/leadership and Corporate Regulatory and Accreditation Services (see Attachment A)/Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.
2. Immediately upon the receipt of any request for copies of patient or business records for use in the investigation of an alleged compliance violation, the Chief Executive Officer/Administrator or their designee must notify the appropriate Division or Regional office/leadership and Corporate Regulatory and Accreditation Services (see Attachment A)/Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.
3. Immediately upon receipt of communication from the facility’s QIO or other health care survey or enforcement agency pertaining to a formal project that will involve aggregate reporting of data or information to the QIO, the facility Ethics and Compliance Officer (ECO) or in the absence of the ECO, the ECO’s designee, must notify Corporate Regulatory and Accreditation Services (see Attachment A)/Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.
4. Upon determination of an adverse event or a violation of a state/federal regulation with an obligation of subsequent notification via self-report communication to the applicable body, the Chief Executive Officer or their designee must notify Corporate Regulatory and Accreditation Services (see Attachment A)/Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.

Following a Survey

- An External Survey Log Data Form (see Attachment B) and any summation notes or summation conference transcript prepared by the facility representative and the surveyor should be completed and sent to Corporate Regulatory and Accreditation Services (see Attachment A).

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- The External Survey Log Data Form is available in electronic format at the Regulatory and Accreditation Services page on Atlas Connect at the following address:
<http://externalsurveylog.app.medicity.net/webforms/newsurvey.aspx>.
 - Copies of any correspondence relating to a survey or an investigation of an alleged violation, whether from the surveying agency, the Centers for Medicare and Medicaid Services (CMS), or any other regulatory agency should be sent to Corporate Regulatory and Accreditation Services (see Attachment A) with reference to applicable log number.
- Corporate Responsibility**
- Corporate Regulatory and Accreditation Services will coordinate with other Corporate, Division, and Regional support functions, upon notification of survey visits or reportable events so that the appropriate Corporate, Division, and Regional Departments may provide the support and guidance.

Corporate Regulatory and Accreditation Services Contact Information

HCA Healthcare Regulatory and Accreditation Services
Attention: REGULATORY COMPLIANCE
One Park Plaza
Nashville, TN 37203

Corporate Regulatory and Accreditation Services:
[Corp HCA Regulatory and Accreditation Services](#)

Phone: (615) 344-5865
Fax: (866) 527-5390

REGULATORY COMPLIANCE NOTIFICATION

Of critical importance is early notification to Division or Regional office/leadership and Corporate management of any investigation of alleged compliance violations. The company policy requires immediate notification to Corporate Regulatory and Accreditation Services and the appropriate Division or Regional office/leadership, as indicated

Please assure this policy is followed in your facility/agency:

1. Immediately upon arrival of any survey team at any HCA Healthcare entity for any reason or the identification of an event for which there is an obligation for reporting to licensure, regulatory or accrediting entity, the Leadership, Chief Executive Officer/Administrator/Facility designee, will notify Corporate Regulatory and Accreditation Services, Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.
2. Complete the [HCA Healthcare External Survey](http://externalsurveylog.app.medicity.net/webforms/newsurvey.aspx) report submission.
<http://externalsurveylog.app.medicity.net/webforms/newsurvey.aspx>
3. With the surveyor's permission, please record any summation conference, which takes place. A copy of the recording should be provided to the surveyor and a copy retained at the hospital for your files.
4. Summation notes by you or the surveyor should be completed and forwarded to Corporate Regulatory and Accreditation Services with reference to the applicable log number as soon as possible after the conclusion of the survey, with a copy to the facility's Division or Regional office/leadership.
5. Following the survey, please immediately forward any subsequent correspondence you receive from the agency, including state survey agencies, CMS, United States Food and Drug Administration (FDA), United States Department of Health & Human Services Office for Civil Rights (OCR), or other entities relating to the survey to Corporate Regulatory and Accreditation Services and your Division or Regional office/leadership with reference to the applicable log number.
6. Upon receipt of any written or verbal request for copies of patient records for purpose of investigation of an alleged violation, the entity should notify the Division or Regional office/leadership and Corporate Regulatory and Accreditation Services.
7. Upon determination of an adverse event or a violation of a state/federal regulation with subsequent notification via self-report communication to the applicable body, the Chief Executive Officer/Administrator or designee must notify Corporate Regulatory and Accreditation Services and the Division Vice President for Quality/Division Quality and Risk Manager for ASCs/Division Quality Manager for PSG.

If you have any questions concerning surveys, reportable events or compliance issues, please contact the Corporate Regulatory and Accreditation Services [mailbox](mailto:CorpHCARegulatoryandaccreditationsurveys@HCAhealthcare.com) at: CorpHCARegulatoryandaccreditationsurveys@HCAhealthcare.com or a Regulatory and Accreditation Services colleague who will assist to assure appropriate communication and access to company resources.

We appreciate your assistance and as always, welcome the opportunity to assist in your endeavors. Please do not hesitate to let us know if there is anything we can assist you with regarding compliance issues (e.g., Occupational Safety and Health Administration (OSHA), Quality Improvement Organizations (QIO), Medicare, state corrective action plans, etc.) or if you need any resources to assist in attaining and maintaining compliance.

SAMPLE

Thank you for logging your external survey. Please note the link for this log has recently been changed and a redirect is currently being used from the prior URL. If you accessed this link from a saved bookmark, we encourage you to update any bookmarks to ensure your ability to access the log once the redirect is removed. If you have any questions or need additional assistance, please email Corp.RegulatoryandAccreditationSurveys@HCAHealthcare.com or call Alec Anderson at (615) 344-1348.

External Survey Log

General

COID #:
 Facility Name:
 State:
 Date(s) Surveyed: thru
(Note: Date format "mm/dd/yy")
 Your Name:
 Your Title:
 Facility Contact Person:
(if follow-up is needed)
 Facility Contact Person's Title:
 Phone Number: ()

Type of Agency

<input type="checkbox"/> AAAHC (Accreditation Assoc. for Ambulatory Healthcare)	<input type="checkbox"/> FBI (Federal Bureau Of Investigation)
<input type="checkbox"/> ACOS (American College of Surgeons)	<input type="checkbox"/> FDA (Food & Drug Administration)
<input type="checkbox"/> ACR (American College of Radiology)	<input type="checkbox"/> Federal Law Enforcement
<input type="checkbox"/> AHCA (Agency for Health Care Administration)	<input type="checkbox"/> Fire Safety Enforcement Agency
<input type="checkbox"/> AOA (American Osteopathic Assoc.)	<input type="checkbox"/> ICE (Immigration and Customs Enforcement)
<input type="checkbox"/> CAP (College of American Pathologists)	<input type="checkbox"/> Joint Commission
<input type="checkbox"/> CHAP (Community Health Accreditation Program)	<input type="checkbox"/> Kentucky OIG (State Agency)
<input type="checkbox"/> CMS / Medicare	<input type="checkbox"/> Local Law Enforcement
<input type="checkbox"/> COC (Commission on Cancer)	<input type="checkbox"/> Nuclear Regulatory Commission
<input type="checkbox"/> DCF (Department of Children and Families)	<input type="checkbox"/> Office of Civil Rights
<input type="checkbox"/> DEA (Drug Enforcement Administration)	<input type="checkbox"/> OIG (Office of Inspector General)
<input type="checkbox"/> Department of Agriculture	<input type="checkbox"/> OSHA
<input type="checkbox"/> Department of Environmental Services	<input type="checkbox"/> QIO (Quality Improvement Organization)
<input type="checkbox"/> Department of Homeland Security	<input type="checkbox"/> State Department of Health
<input type="checkbox"/> Department of Transportation	<input type="checkbox"/> State Department of Human Services
<input type="checkbox"/> Environment Protection Agency	<input type="checkbox"/> State Law Enforcement
<input type="checkbox"/> FACT (Foundation for the Accreditation of Cellular Therapy)	<input type="checkbox"/> Other: <input type="text"/>

Type of Survey

Accreditation Survey
 Type:

Validation of TJC Triennial by State Survey Agency/CMS

Annual Relicensure

Complaint from Competitor

Complaint from Employee

Complaint from Family

Complaint from Nursing Home

Complaint from Patient

Complaint from Physician

EMTALA / COBRA

FDA Inspection:
 IRB Blood Equipment Pharmacy Recall

Other Type of Survey:

Follow-Up of Original Accreditation Survey
 Type:

Original Survey Date(s):

Hazardous Waste

Laboratory

NRC (Nuclear Regulatory Commission)

Pharmacy/Sterile Compounding

Radiation Safety

Risk Management

State for CMS

TJC/DNV Disease-Specific Certification

Type of Surveyor

TOTAL Number of Surveyors On-Site: (if none enter zero)

Indicate the number of surveyors according to discipline:

<input type="checkbox"/> Administrator	<input type="checkbox"/> Physician
<input type="checkbox"/> Dietician	<input type="checkbox"/> Plant Operations / Engineering
<input type="checkbox"/> Fire Marshall	<input type="checkbox"/> Psychologist
<input type="checkbox"/> Home Health Aide	<input type="checkbox"/> Radiation Physicist
<input type="checkbox"/> Human Services Specialist	<input type="checkbox"/> Records Administrator
<input type="checkbox"/> Laboratorian	<input type="checkbox"/> Sanitarian
<input type="checkbox"/> Licensing Counselor	<input type="checkbox"/> Social Worker
<input type="checkbox"/> Life Safety Administrator	<input type="checkbox"/> Therapist
<input type="checkbox"/> Nurse	<input type="checkbox"/> Joint Commission: Surveyor Name(s):
<input type="checkbox"/> Environmental Specialist	<input type="text"/>
<input type="checkbox"/> Other: <input type="text"/>	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>

Type of Area

<input type="checkbox"/> Accreditation Survey	<input type="checkbox"/> Mammography
<input type="checkbox"/> Admitting	<input type="checkbox"/> Medical Records/HIM
<input type="checkbox"/> Ambulatory Service Center (ASC)	<input type="checkbox"/> Medical/Surgical Nursing
<input type="checkbox"/> Behavioral Health/Psychiatric Services	<input type="checkbox"/> Non-Hospital Related
<input type="checkbox"/> Biohazardous Waste	<input type="checkbox"/> Non-Invasive Cardiology
<input type="checkbox"/> Cath Lab	<input type="checkbox"/> Nursing: <input type="text"/>
<input type="checkbox"/> Credentialing	<input type="checkbox"/> Oncology
<input type="checkbox"/> Discharge Planning	<input type="checkbox"/> Outpatient Services
<input type="checkbox"/> Emergency Services	<input type="checkbox"/> Outpatient Therapy Services
<input type="checkbox"/> Federal, State & Local Laws	<input type="checkbox"/> Peer Review
<input type="checkbox"/> Food Services	<input type="checkbox"/> Pharmaceutical Services
<input type="checkbox"/> Geropsychiatric Unit	<input type="checkbox"/> Physical Environment
<input type="checkbox"/> Governing Body	<input type="checkbox"/> Privileging
<input type="checkbox"/> Home Health Services	<input type="checkbox"/> Quality Assessment
<input type="checkbox"/> Hospice	<input type="checkbox"/> Radiologic Services / Diagnostic Imaging
<input type="checkbox"/> Human Resources	<input type="checkbox"/> Rehabilitation Services
<input type="checkbox"/> Hyperbaric Oxygen Therapy (HBO)	<input type="checkbox"/> Respiratory Services
<input type="checkbox"/> Infection Control	<input type="checkbox"/> Skilled Nursing Unit
<input type="checkbox"/> Intensive Care	<input type="checkbox"/> Social Services
<input type="checkbox"/> Labor & Delivery	<input type="checkbox"/> Surgical Services
<input type="checkbox"/> Laboratory Services	<input type="checkbox"/> Transplant Program
<input type="checkbox"/> Other: <input type="text"/>	

All Surveys

Status at termination of visit:

Check the box for each applicable statement:

Immediate Jeopardy. (Explain below)

Plan of Correction required.

Referred to another external agency.

We anticipate subsequent visit(s) related to this survey.

Civil Monetary Penalty. Amount: \$ State Federal

OSHA Monetary Penalty. Amount: \$ State Federal

Do you need assistance or support in follow-up of the survey?
If so, please specify the services or support needed:

Additional comments, concerns or requests:

CMS/State Surveys
If an EMTALA/Complaint survey, was EMTALA/Complaint validated?

OSHA Surveys
If an informal conference was requested, please describe the outcome:

Print this completed form before clicking submit button.

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