



Center for Health Care Quality General Acute Care Hospital Relicensing Survey Process Guidance

Definition of a General Acute Care Hospital (GACH)

A GACH means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services (Health and Safety Code §1250(a)).

Authority

Health and Safety Code §1254 provides that the California Department of Public Health (CDPH), Licensing and Certification Program (L&C) has the authority to inspect and license health facilities to provide their respective basic services and to approve a general acute care hospital to provide special services.

Health and Safety Code §1279 provides that every health facility for which a license or special permit has been issued shall be periodically inspected by the department or by another government entity under contract with the department. Inspections shall be conducted no less than every three years and as often as necessary to ensure quality of care.

The statutory requirements for GACH licensure are defined in California Health and Safety Code, Division 2, Chapter 2, Articles 1 through 10, and Chapter 2.05, as well as additional sections identified in the GACH Comprehensive Licensing Survey Guidelines.

The regulatory requirements for GACH licensure, including supplemental service approval are defined in Title 22, California Code of Regulations, Division 5, Chapter 1, relating to General Acute Care Hospitals, §70001-70923.

Purpose of GACH Relicensing Survey

The purpose of a GACH Relicensing Survey is to promote quality of care in hospitals, verify compliance with state statutes and regulations, and ensure a program wide consistency in the hospital survey methodology. In order to ascertain compliance, hospitals are surveyed no less than every three years using the GACH Relicensing Survey. The GACH Relicensing Survey incorporates elements of the former stand-alone Medication Error Reduction Plan (MERP) survey and Patient Safety Licensing Survey (PSLS).

The GACH Relicensing Survey will not be used in place of the GACH Initial Licensing Survey.

Survey Protocol

All GACH Relicensing Surveys shall include, but not be limited to the facility's compliance with statutory and regulatory requirements of licensure, particularly those addressing quality of care. Each survey will consist of a review of nursing services, pharmacy, and identified compliance concerns obtained during offsite preparation. CDPH will not provide GACHs with advance notice of the survey.

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Survey Team

Composition. The recommended team size shall be comprised of a Registered Nurse, Medical Consultant*, and Pharmaceutical Consultant. At least one member of the team must have knowledge and experience in evaluating hospital administration and environmental inspections. Additional members will be added based on the size of the hospital, facility's compliance history, number and complexity of approved supplemental services, distance of locations that will be visited during the survey, and if indicated, those with subject matter expertise to evaluate facility operations (e.g. nutrition consultant, medical record consultant, rehabilitation therapist, Life Safety Code personnel, etc.).

Size. Team size is based upon the number of beds, number of campuses, units/locations, services to be surveyed, compliance history, and other pertinent factors. To determine the team size and composition, the initial team size starts with the following:

Size of Hospital	Recommended Minimum Survey Team
Small – 100 beds or less	<ul style="list-style-type: none">• Registered Nurse (RN) (Team Coordinator)• Medical Consultant *• Nutrition Consultant*• Pharmaceutical Consultant• Additional RN surveyor with experience, if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment• Additional team members as indicated
Medium – 101 -199 beds	<ul style="list-style-type: none">• Registered Nurse (RN) (Team Coordinator)• Medical Consultant *• Nutrition Consultant*• Pharmaceutical Consultant• Two additional RN surveyors, at least one with experience, if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment• Additional team members as indicated

Size of Hospital	Recommended Minimum Survey Team
Large – 200 or more beds	<ul style="list-style-type: none"> • Registered Nurse (RN) (Team Coordinator) • Medical Consultant * • Nutrition Consultant* • Pharmaceutical Consultant • Three additional RN surveyors, at least one with experience if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment. Additional team members as indicated

* Medical Consultant and Nutritional Consultant may be onsite or remote.

Survey Team Coordinator

The GACH Relicensing Survey is performed under the leadership of a Team Coordinator. The Team Coordinator is responsible for ensuring that all survey preparation and survey activities are completed.

The responsibilities of the Team Coordinator include, but are not limited to:

- Scheduling the date and time of the survey activities
- Serving as spokesperson for the team
- Planning and coordinating survey plan, including identifying team members' responsibilities.
- Assist with managing process and time
- Fostering on-going communication among team members and hospital staff.
- Evaluating team progress and coordinating daily team meetings
- Coordinating any on-going conferences with hospital leadership and providing on-going feedback, as appropriate to hospital leadership on the status of the survey
- Coordinating Entrance Conference
- Facilitating Preliminary Decision Making
- Coordinating Exit Conference
- Coordinating the preparation of the Statement of Deficiencies and any other Task 6 documentation
- Delegating any items to survey team members as needed

When is a GACH Relicensing Survey indicated?

- No less than every three years; and/or,
- As often as necessary to ensure quality of care

Task 1 Off-Site Survey Preparation

The purpose of this task is to analyze information about the hospital in order to develop a plan for investigation that considers both the best approach for inspecting the facility's unique layout and/or multiple campuses, and that will address any identified areas of potential concern.

Pre-Survey Analysis and Planning

The Team Coordinator should review and consider any past non-compliance trends or recurrent issues as can be identified in the hospital's facility file and/or are available in the databases available to L&C surveyors. The following lists are intended to help to identify documents or information that the Team Coordinator should review and/or provide to the other team members, as may be useful to the team. The district office support staff should be notified of the survey, and produce a survey shell to include team member names and all applicable regulation sets.

Information from Hospital's File: License

- Basic services and supplemental services
- Number of beds, including any that may be on suspense
- Outpatient services
- Facility layout (including any negative pressure rooms) and locations of outpatient services
- Program flexibility approvals
- New construction or services
- Hospital website

Information from Hospital's File: Past Three Years' Compliance

- Substantiated adverse events
- Administrative Penalties (Breaches, Immediate Jeopardy, Failure to Report)
- Medication Error Reduction Plan surveys
- Complaints and Entity Reported Incidents (ERIs) (note locations of any complaint related to failure to meet the staffing ratios)
- Patient Safety Licensing Survey
- ELMS facility profile report
- Current situation reports
- Recertification or validation surveys (particularly any Condition Level findings)

Documents for Team members

- Facility license
- Facility layout (determine the number of campuses to be surveyed)
- Other documents as needed

Off-Site Survey Team Meeting

The Team Coordinator will convene an off-site meeting (may be a teleconference) in advance of the survey with as many of the survey team members as possible. During this meeting, the Team Coordinator will provide information about and facilitate discussion of the survey plan. This may include, but is not limited to:

- Written summary of identified issues for team members
- Process of General Acute Care Relicensing Survey and all relevant (and available) survey tools
- Survey roles and responsibilities for each team member
- The list of required hospital documents that the Team Coordinator will provide the hospital administration upon entrance

- Number of and type of patient assignments/units to be surveyed based on compliance history, and other areas of concern
- Pertinent State and Federal Statements of Deficiencies/Plans of Corrections (POCs)
- Means of contact for all team members during the survey (best telephone numbers, email addresses, etc.)
- Date, location and time team members will meet to enter the facility
- Date, location and time for the daily team meetings
- Potential exit date and time for the exit conference
- Post-survey document preparation timelines and expectations

Task 2 Entrance Activities

The purpose of this task is to explain the survey process to the hospital, introduce the survey team members, and to obtain information needed to conduct the survey.

Arrival

The entire survey team should enter the hospital together, and the surveyors should present their business cards/identification. The Team Coordinator will inform the hospital administrative designee in charge at the time of entrance that a General Acute Care Relicensing Survey is being conducted.

Entrance Conference

The entrance conference sets the tone for the entire survey. The team must be courteous and professional when requesting items needed for the team. The entrance conference should be specific, brief, and concise. Introductions of the survey team can be done by the Team Coordinator or by the individual survey team members. If other disciplines/consultants are to join the survey at a later time, inform the hospital's administration.

During the entrance conference, the Team Coordinator will:

- Introduce members of the survey team
- Explain the purpose and scope of survey
- Explain the survey process, the facility and file access that surveyors must have, and the confidentiality of interviews with patients, family, and staff
- Provide the general schedule of services to be reviewed during the survey
- Provide the Entrance List
- Determine how surveyors will access electronic medical records (EMR) and request staff resources to assist surveyors
- Verify licensing information and services
- Request a meeting area for the survey team to use during the survey
- Request a conference call system, if necessary, when more than one campus in a consolidated license is being surveyed to facilitate communication

Hospital Tours

A group tour of the hospital could consume a number of hours allocated to conduct the survey. Refrain from engaging in formal hospital guided tours.

Team Meeting

After the entrance conference with the hospital administrative staff, the team will evaluate the information gathered and modify the surveyor assignments as needed. During this on-site team meeting, the team members will:

- Review the scope of hospital services
- Identify/confirm hospital locations to be surveyed, including any off-site locations
- Set the next team meeting time and date

Additionally, the Team Coordinator will remind all team members that observations drive the investigation and survey process and that they are to:

- Follow sampled patients through hospital settings: surgery, radiology/imaging, etc. to determine appropriateness of the care and services rendered
- Observe individual treatments, care, and interaction with hospital staff
- Review closed records as indicated or if no open records are available

Sample Size and Selection

In selecting the patient sample, the individual surveyors will select patients from the service areas to which the surveyors are assigned. The patient selection should represent a cross-section of the patient population and the services provided by the facility. A total sample size will consist of 6 to 10% of the current inpatient census with a minimum of 30 patients for patient record review, and expand the sample size as necessary. For a facility with an inpatient census of fewer than 30 patients, the minimum sample selection of 30 patients shall include closed records.

Whenever possible, select patients who are in the facility during the time of the survey. Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through observations, record reviews, and interviews with patient/staff/family.

Observations of the sample patient will determine how the surveyor proceeds with patient reviews and surveying units/locations and services.

Task 3 Information Gathering/Investigation

The purpose of this task is to determine compliance with the statutory and regulatory requirements for GACH relicensure and/or supplemental service approval in California. The survey team will perform this task through observation, interviews, and document review.

During the Survey

In performing this task, all members of the survey team are expected and required to:

- Focus attention on actual and potential patient outcomes and patient safety, as well as, required processes. In the case of findings of patient harm, the team should consider the severity and scope of the harm

- Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations
- Visit patient care settings as decided by the survey team, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
- Observe the actual provision of care and services to patients and the effects of that care in order to assess whether the care provided meets the needs of the individual patient
- Bring significant issues or adverse events to the Team Coordinator's attention immediately. Use the State IJ Policy and Procedure (P&P) if Immediate Jeopardy is suspected
- Respect patient privacy and maintain patient confidentiality at all times
- Be in daily contact with the Team Coordinator and other team members (ideally at a daily team meeting) to communicate survey progress and areas of concern
- Maintain a professional working relationship with facility staff, including conferencing with facility staff regarding survey findings (which may allow them to present additional information or offer explanations for identified issues)
- Exercise discretion as to whether to allow facility staff to accompany surveyors performing survey tasks

Survey Locations

Survey departments, services, and locations that are identified on the facility license. Decide as a team which units/services will be visited in order to address compliance decisions.

- The consideration to visit services and locations could include: departments, services, and locations on the primary hospital campus and/or immediately adjacent to the primary hospital campus
- Inpatient care locations of the hospital
- Outpatient surgery locations of the hospital
- Locations where complex outpatient services, including emergency care, is provided by the hospital
- Supplemental service locations

Additional sites may be added, depending on how sampled patients interact with hospital services and/or if the team becomes aware of off-campus services to which licensing requirements apply that are not identified on the facility license.

Patient Review

The hospital survey should include a comprehensive review of basic care and services received by each patient in the sample. This entails:

- Observations of care/services provided to the patient
- Patient and/or family interview(s)
- Staff interview(s)
- Medical record review

The data gathered from these means must be integrated to develop the survey findings.

Observations. Observation is the best means of collecting first-hand knowledge of hospital practice. Surveyors should remain alert to all opportunities to note observations relevant to patient care, regardless of the specific activity in which they are engaged. For example, while conducting a chart review, a surveyor should simultaneously remain alert to the environment and patients in the surveyor's immediate vicinity, noting staff interactions, as well as, safety hazards or infection control practices employed. Additionally, surveyors should take all opportunities to note observations regarding staffing sufficiency, equipment condition, building structure, sounds and smells, and the security and confidentiality of medical records.

Observations must be noted with as much detail as possible. The following data are especially important to document: the date and time of observation; location; individuals present during observation; and activity being observed (such as the type of treatment modality, therapy, etc.). The validity of a surveyor's observation is greatly increased by verification. Surveyors are encouraged to verify their observations with the patient, family, facility staff, other survey team members, or by other means. For example, a surveyor who observed administration of an outdated medication should validate the observation by asking a nursing staff member to verify that the drug is outdated.

Except in certain circumstances, surveyors must not examine patients in order to determine the patient's health status or assess whether appropriate health care is being provided. Acceptable circumstances include ensuring a patient's welfare where he/she appears to be in immediate jeopardy. When a patient's examination is relevant to the survey, the surveyor may request that a patient is examined by a staff member of the facility in the surveyor's presence, but only after obtaining the patient(s)/family(ies) permission. The health and dignity of the patient must always be the survey team's first concern. Surveyors must respect a patient's right to refuse to be examined.

When a patient does provide permission, surveyors must:

- Introduce him/herself to the patient
- Interview the patient, staff, and family members, as appropriate, to determine if care needs are being met and verify observations

Interviews. Interviews are another method for collecting information and are useful for verifying or validating information obtained through observations. Throughout the survey, surveyors should take every opportunity to conduct informal interviews for the purposes of determining what additional observations, interviews, and record reviews may prove useful.

When conducting patient interviews, it is essential that the interviews are conducted in private and with the patient(s)/family(ies) prior permission. Patient interviews should include questions specific to the patient's condition, reason for hospital admission, quality of care received, and the patient's knowledge of their plan of care. For instance, a surgical patient should be asked about the process for surgery preparation, his or her knowledge of and consent for the procedure, pre-operative patient teaching, and post-operative patient goals and discharge plan. In general, all patient interviews should include questions designed to assess patients' knowledge of their plans of care, the implementation of those plans, and the quality of the services received. It is also important to ask questions of both patients and family members regarding their knowledge of patient rights, advanced directives, and the facility's grievance/complaint procedure.

When conducting staff interviews, it is important to elicit the desired information quickly and succinctly, out of respect for staff time and in order to return them to patient care. Taking the time to

anticipate the most effective phrasing is worthwhile. For example, a surveyor attempting to determine whether a staff member is aware of the facility's policy for reporting medication errors and his/her role in such an event, could ask, "If you became aware that a patient had received a medication that was not prescribed for them, what would you do?" Interviews with direct care staff should be directed at obtaining information of the patient's needs, plans of care, and progress toward goals. Further, it is important to address problems or concerns identified during a patient or family interview in the staff interview in order to validate the patient's perception or to gather additional information.

The following are important additional considerations for ensuring the validity of data collected by interviews:

- Surveyors must maintain detailed documentation of each interview conducted, including: the interview date, time, and location, the full name and title of the person interviewed, and key points made and/or topics discussed. Whenever possible, document the exact words used by the interviewee
- When evaluating patient care, be sure to include interviews with staff who work most closely with the patient
- Ask open-ended, non-leading questions or rephrase the question(s) to obtain the needed information
- Validate all information obtained, either by verifying that it is consistent with other interviews, or supported by observation and documentation
- To the extent possible, conduct all interviews in-person. Telephone interviews should only be conducted if necessary

Document Review. Document review is essential to validate data obtained through observations and interviews for the purposes of evaluating hospital compliance with the requirements for licensure. Surveyors should obtain copies of all documents needed to support survey findings. If a digital or electronic record is viewed and a copy is requested, verify that the copy provided is identical to the record before exiting the facility.

When conducting document review, it is important that the surveyor notes the source and date of any documents and records received.

The following are some examples of documents that the survey team may need to review and, as necessary, to demonstrate noncompliance, obtain copies:

- Patient's clinical records, to validate information gained during the interviews, as well as, for evidence of advanced directives, discharge planning instructions, and patient teaching. This review will provide a broad picture of the patient's care
- Plans of care and discharge plans that demonstrate whether they have been initiated immediately upon admission and modified as patient care needs change
- All of the relevant documentation for each stage of a patient's progress through a process of care. For example, record review for a sampled surgical patient would include the pre-surgical assessment, informed consent, anesthesia notes, etc., as needed.
- Personnel files to determine if staff members have the appropriate competencies, have had the necessary training required, and are licensed, if it is required

- Credential files to determine if the facility follows its own written policies for medical staff privileges and credentialing
- Maintenance records to determine if equipment is periodically examined and in good working order, and if environmental requirements have been met
- Staffing documents to determine if adequate numbers of staff are provided according to the number and needs of the patients
- When reviewing applicable policy(ies) and procedure(s), ensure the material is current and up to date

Task 4 Preliminary Decision Making and Analysis of Findings

The purpose of this task is to assist the team in preparing the exit conference report by beginning an analysis of findings and preliminary decision-making. Depending on the team's decisions, this task will identify any additional activities that may need to be initiated.

Discussion Meeting

The Team Coordinator will schedule this meeting to occur after the survey team assignments have been completed. All team members are required to attend, if at all possible. Prior to the meeting, each team member should review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team.

During the meeting, surveyors will share their findings, evaluate the evidence, and make team decisions regarding the facility's compliance with the requirements of licensure. For any issues of noncompliance, the team needs to reach a consensus.

The team must assure that their findings are supported by adequate documentation of observations, interviews, and document reviews, including any needed evidence such as photocopies. At the discussion meeting, the team will also determine which team members will be responsible for presenting certain areas of findings during the exit conference. During this meeting, the team should also discuss any difficulties anticipated during the exit conference based on interactions during the survey. The presentation of findings should be concise and factual, and presented in a professional manner. If the team anticipates that the exit conference will be contentious, the Team Coordinator should contact the supervisor.

Determining Deficiencies

Each deficiency of hospital licensing requirements occurring on or after April 1, 2014 must be evaluated to determine whether an administrative penalty for the deficient practice will be applied. Per Title 22, Division 5, Chapter 1, Article 10, any deficiency that the survey team agrees is more than a minor violation, should be considered for an administrative penalty. For situations/events that may result in death, serious injury, or potential for serious injury or death, see P&P 800.3.3 (GACH State Administrative Penalty Process for Immediate Jeopardy Violations) to determine if the deficiency should be considered for an Immediate Jeopardy (IJ) Administrative Penalty (AP). For situations/events that do not rise to the level of an IJ AP, but result in patient harm, potential for more than minimal patient harm, or patient financial harm, see P&P 800.3.7 (GACH State Administrative Penalty Process for Non-Immediate Jeopardy Violations) to determine if the deficiency should be considered for a Non-IJ AP. Both P&P 800.3.3 and 800.3.7 are available at:

<http://cdphintranet/sites/Incintranet/Pages/PPManualVolumeandFacilityType.aspx>.

Other Deficiency Issues to Consider

- If the survey team discovers any adverse events, the team shall identify if the adverse event was reported to the Department. If the adverse event was not reported to the Department, verify whether the patient was notified and the date the adverse events should have been reported to the Department. See H & S Code 1279.1 Adverse Events. Hospitals are required to report an adverse event:
 - If the adverse event was an on-going urgent or emergent threat to the welfare, health or safety of patients, personnel or visitors, not later than 24 hours after the hospital has detected the adverse event
 - In all other circumstances, not later than five (5) days after the hospital detected the adverse event
- If the survey team discovers deficient practices that rise to a Federal Condition of Participation level of non-compliance, inform your District Office supervisor, so that they may communicate with the Federal Regional Office for further instructions

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the team should decide the best way to conduct the additional review prior to the exit conference.

Task 5 Exit Conference

The purpose of this task is to inform the facility staff of the team's preliminary findings, which will be finalized in Task 6.

Exit Conference Preparation

All team members should attempt to attend the exit conference in person. If necessary, some team members may conduct their exit conference ahead of the team with administration or participate remotely. The Team Coordinator has responsibility for organizing the presentation of material and information to be shared during the exit conference.

During the Exit Conference

The following principles apply when conducting the exit conference:

- Thank everyone for their cooperation during the survey
- Introduce all team members, mentioning any that have concluded their portion of the survey and have left the facility
- Request that all facility representatives introduce themselves. Note: The facility determines which hospital staff will attend the exit conference. This may include the facility's attorney
- Explain that the exit conference is a meeting to present preliminary findings subject to District Office supervisory review and approval
- Advise that official findings will be presented in writing on the Statement of Deficiency and will be mailed within approximately 10 working days to the facility
- Clarify that the provider will have an opportunity to present any new or additional information and/or evidence of compliance for consideration prior to the team exiting the facility

- Explain any ground rules and how the team will present the preliminary findings. Ground rules may include waiting until the surveyor and/or team finishes discussing the deficiencies before accepting comments from facility staff
- Present the findings of noncompliance, including the basis of the findings with enough information for the facility to initiate their plan of correction. Avoid referring to specific regulatory section by number, unless requested
- Do not reveal the identity of an individual patient or staff member in discussing survey results. Identity includes not only the name of an individual patient or staff member, but also includes any reference by which identity might be deduced
- Refrain from making any general comments (e.g., "Overall the facility is very good"). Stick to the facts
- If an immediate jeopardy or non-immediate jeopardy deficiency was identified during the survey, use the exit script provided in the P&P for GACH Administrative Penalty State Immediate Jeopardy (800.3.3), attachment B, or GACH Administrative Penalty State Non-Immediate Jeopardy (800.3.7), attachment B, available at: <http://cdphintranet/sites/Incintranet/Pages/PPManualVolumeandFacilityType.aspx>
The facility must be informed that an administrative penalty may be imposed.
- At the conclusion of exit conference, request that the facilities complete the " GACH Comprehensive Licensing Survey Evaluation Form"—indicate that submission of this form is voluntary, but important to CDPH in its own quality improvement processes

Discontinuation of an Exit Conference

Surveyors may choose to interrupt or halt the exit conference when the facility or its attorney is creating an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference.

Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the District Office for further direction. If appropriate, the entire survey team should leave the facility until further direction is provided.

Recording the Exit Conference

If the facility wishes to record the conference, it must agree to do so in a manner that will produce two identical copies of the recording immediately following the exit conference's conclusion. The surveyors should take one copy with them at the conclusion of the conference. It is at the sole discretion of the surveyor(s) to determine if videotaping is permitted. Videotaping is permitted if it is not disruptive to the conference, and a copy is provided at the conclusion of the conference.

Exit Survey Conclusion

All team members should leave the facility together immediately following the exit conference. The Team Coordinator should decide the best way to conduct the further review if the facility provides additional information.

Task 6 Post Survey Activities

The purpose of this task is to complete the licensing survey.

Completion of Survey Activities

The survey team completes the written Statement of Deficiencies so that it can be mailed to the facility within 10 business days from the date of the exit conference. The district office will transmit the Statement of Deficiencies with a letter that indicates the facility's timeline to submit a Plan of Correction, the requirements of an acceptable Plan of Correction, and a notice of intention to issue any Administrative Penalties, if applicable.

Upon receipt of the facility's Plan of Correction, the district office will review and provide the facility with a response indicating approval of the Plan of Correction or identify areas requiring further development or clarification and request that the facility resubmit an appropriate Plan of Correction.

Issuance of Administrative Penalties

Any deficiency occurring on or after April 1, 2014, for which the survey team agrees, has more than a minimal relationship to the health or safety of hospital patients shall be considered for an administrative penalty (Title 22, Division 5, Chapter 1, Article 10). For further guidance, consult the respective P&Ps regarding the process of preparing and issuing administrative penalties. For immediate jeopardy deficiencies see P&P 800.3.3 and for non-immediate jeopardy deficiencies see P&P 800.3.7. Both P&Ps are available at:

<http://cdphintranet/sites/Incintranet/Pages/PPManualVolumeandFacilityType.aspx>.