

Executive Summary

The Joint Commission enterprise provides a wide variety of products and services to its customers and to the general public, all of which aim directly to continuously improve the quality and safety of health care and inspire healthcare organizations to excel in providing safe and effective care. The Joint Commission enterprise consists of three separate, not-for-profit companies that share the same vision. The Joint Commission is an Accrediting Organization (AO), providing accreditation and certification services to more than 22,000 healthcare organizations and programs in the United States. Joint Commission Resources (JCR) and the Joint Commission Center for Transforming Healthcare (the Center) are not-for-profit affiliates of the Joint Commission, each with its own Board of Directors.

The Joint Commission does not provide any fee-based consulting services. JCR does provide fee-based consulting services to assist healthcare organizations in meeting accreditation standards. The Center provides fee-based training in process improvement methods unrelated to accreditation standards.

The Joint Commission enterprise believes that ensuring the integrity of the accreditation process is of the utmost importance. An essential component of that integrity is that accreditation must be free of the appearance or reality of any potential conflict of interest. The enterprise achieves that goal by prohibiting the exchange of any information about healthcare organizations between the AO and the organization that provides consulting services to assist organizations in standards compliance. To effectuate that prohibition, we have created and maintained a robust combination of structural, policy, and procedural safeguards (collectively known as the firewall), which are described in more detail below.

The Joint Commission enterprise provides many other products and services that do not fall into the category of fee-based consulting. The Joint Commission produces many products that are free to all. For example, Sentinel Event Alerts (which highlight important quality problems and present summaries of improvement strategies), Quick Safety publications (brief descriptions of pressing patient safety issues), and Speak Up campaign materials (multi-media advisories geared to help patients and their advocates become active partners in their health care) are all available on the Joint Commission's public website at no charge. In addition, Joint Commission staff regularly publish articles in peer-reviewed journals on various quality and safety subjects.

As mentioned above, JCR provides fee-based consulting services related to accreditation standards. Among the structural safeguards that contribute to the effectiveness of the Firewall program, JCR was created as a separate corporate entity, with its own Board of Directors and its own staff. In addition, JCR's offices are located in a separate building, about 3 miles from the Joint Commission Central Office. In addition to accreditation preparation consulting, JCR also provides a host of hard copy and electronic publications on a wide array of healthcare quality and safety issues. While most of them are available for purchase, some are free and available to all on JCR's public website. JCR also offers electronic products to customers that assist them in assessing their organization's compliance with accreditation requirements. JCR conducts educational programs on a variety of topics that are attended by many individuals from many different types of healthcare organizations.

The Center's mission is to help healthcare organizations pursue zero harm and achieve high reliability. The Center has produced several tools that are made available to Joint Commission-accredited healthcare organizations at no cost—as part of the accreditation program. Those tools include software modules (Targeted Solutions Tools or TST®s) to help achieve extremely high levels of performance on hand hygiene compliance, preventing falls with injury, improving hand-off communications, and improving surgical safety. The Center has defined a roadmap for healthcare organizations to use as a guide to achieve zero harm. That roadmap identifies essential components of leadership action, organizational culture, and process improvement tools and methods all of which are necessary to pursue high reliability. The Center has created a self-assessment tool (Oro®2.0) that hospital leadership teams use to evaluate their progress toward high reliability on 14 specific components of the roadmap. Like the TSTs, Oro2.0 is available to all Joint Commission-accredited hospitals at no charge.

The Center also provides several fee-based services. None of them are designed to assist accredited organizations in complying with accreditation standards and, thus, those services do not fall within the organization's Firewall policies. These services include training in a variety of performance improvement tools and methods, including lean, six sigma, and change management, and how to apply them to improve healthcare quality and safety. Center staff also assist organizations requesting help in implementing the TSTs or in conducting an Oro2.0 assessment. All of these engagements (as well as the no-charge use of the TSTs and Oro 2.0) are governed by confidentiality agreements between the Center and healthcare organizations, which serve to create the open and candid relationship that is necessary for successful collaborative quality improvement.

There are risks of a conflict of interest when any AO considers providing accreditation-related consulting. However, The Joint Commission's 30-year track record has demonstrated that appropriate and effective policies and procedures prevent both the perception and reality of conflicts that might jeopardize the integrity of the accreditation process. The benefits of safer, higher quality patient care considerably outweigh the small, residual perception of potential risk, particularly when such risks are mitigated by a robust Firewall compliance program such as the one The Joint Commission has established.

A. Public/Stakeholder Feedback

A.1. *We are seeking comment of the type of fee-based consulting services provided by the AOs to the facilities they accredit. How are these services provided and communicated to the facilities? Are potential conflicts of interests disclosed?*

The Joint Commission's highest priority is to maintain the integrity of its accreditation process. Since 1987, shortly after the establishment of a separate corporation-- now called Joint Commission Resources (JCR)--a set of operating guidelines, including clear limitations on scope of services was established to eliminate any real or perceived conflict of interest between The Joint Commission's accreditation activities and consultative technical assistance services provided by JCR. These guidelines evolved into a robust Firewall Policy, which has been strengthened over the years, most significantly in 2005, to provide even greater controls of separation. At that time, The Joint Commission instituted board-level oversight processes for approval of any Firewall Policy changes and began to retain external third-party auditors to test compliance with the Policy and its related procedures. These tests are completed biennially by external auditors with robust internal reviews performed between those years. This oversight and accompanying processes remain in place today. (Also, see section A.6. for additional details of the Firewall Policy.)

The structures and processes implemented and monitored by The Joint Commission and JCR to prevent any sharing of confidential consulting information with Joint Commission accreditation personnel are necessary for preventing any real or perceived conflict with the provision of consulting services. Firewall Policies and Procedures have been tested by independent, external auditors and by the Government Accountability Office (GAO).

All Joint Commission surveyors are employed by the accrediting organization and are prohibited from conducting any kind of consulting related to assisting healthcare organizations to comply with accreditation requirements. The Firewall Policy prohibits JCR consultants from:

- Being present during any discussions or meetings in which confidential information to which they are not entitled to have access is discussed.
- Assisting accredited organizations with the following (that other non-JCR consultants can):
 - Challenges to accreditation decisions or findings of The Joint Commission.
 - Preparing evidence of standards compliance documents.
 - Preparing letters that challenge Requirements for Improvement (RFIs).
 - Preparing reports, documents, or presentations to be used in connection with any review hearing or appeal.
- Being in contact with an organization at any time during the organization's on-site survey.
- Staying on premises during a Joint Commission survey.
- Communicating any organization-specific information, obtained during a consulting engagement, to Joint Commission accreditation personnel.

The Policy recognizes that a healthcare organization that retains JCR consultants might attempt to influence a Joint Commission surveyor by informing the surveyor that the organization did engage in a consulting arrangement with JCR. Surveyors are instructed to tell the organization that such information is not relevant to their survey work. Further, surveyors may not transmit that information to the Joint Commission Central Office, where all final accreditation decisions are made. Thus, the key accreditation decision makers, all of whom are located in the Central Office, are prevented from receiving information about JCR consulting customers---even from those customers themselves.

JCR provides several types of consulting services in which highly knowledgeable consultants work with individual healthcare organizations to assist them in how to comply with Joint Commission and CMS requirements and to stay in continuous compliance. The Joint Commission enterprise's robust approach to address any real or perceived conflict of interest is communicated to the field in these ways:

- All consulting contracts include explicit language outlining the limitations on scope of services and handling of confidential information required by the Firewall Policy (including the activities JCR consultants may not undertake noted in the bulleted paragraph above).

- The JCR website and all JCR marketing materials include the following statement in any area that mentions consulting services: *“The use of Joint Commission Resources (JCR) consulting services is not necessary to obtain a Joint Commission Accreditation award, nor does it influence the granting of such awards.”*
- JCR consultants communicate directly with clients before and throughout on-site engagements that the organization-specific information they discuss is not shared with The Joint Commission accreditation entity and that the use of consulting services does not in any way impact accreditation.
- Consulting staff receive updated training annually on the Firewall Policy and related policies; this training is mandatory.
- The Corporate Compliance and Privacy Officer manages the Firewall Compliance Program.

Additionally, JCR does not disclose the names or identifiers of any facilities or organizations that have received JCR services to The Joint Commission because this information is considered confidential under the Firewall Policy.

A.2. *Training providers and suppliers of services on the applicable requirements for Medicare certification is an important function to improve quality of care. Are there other entities that could provide this training besides the AOs?*

The Joint Commission believes that accrediting organizations should not directly provide fee-based assistance to health care organizations on how to comply with accreditation requirements. Separating the accreditation function of an AO from any related entity that provides accreditation-related consulting in a manner such as described in these comments is essential to the integrity of both processes. This is why JCR was established. Of course, entities that are not AOs may (and do) also provide such consulting services. However, such entities need to have the capability to provide accurate, timely, and effective training on the applicable requirements for Medicare certification. They must have up-to-date knowledge on Medicare statutes, rules and interpretative guidance, and must have extensive expertise in boots-on-the-ground assessment of compliance against health and safety standards.

JCR meets these requirements and goes well beyond them. JCR invests significant effort to have the best trained, most experienced consultants. All JCR consultants meet strict requirements for high levels of expertise and experience: an average of 10-15 years of prior experience working in healthcare organizations related to accreditation and healthcare quality improvement. Currently, 71 advanced degrees in healthcare are represented on the consultant team.

JCR is also qualified to serve as a CMS Systems Improvement Agreement partner and has delivered critical and urgent improvement advice and assistance to healthcare entities; these services have been essential to help such organizations continue to serve patients where access to high quality of care is a dire need. JCR has also assisted with informing various agencies of the federal government about gaps in compliance with accreditation and federal health and safety standards. Such support is critical to help these entities continue to provide safe and high-quality healthcare to underserved populations across the U.S.

This cross-mixing of specialties allows JCR a unique perspective that serves clients well in solving their most pressing issues. JCR consultants have worked with organizations for decades and have become the consistent force for education and improvement in these organizations as their accreditation managers change every few years.

There is an absolute need for a consulting entity of this nature to maintain ongoing currency with changing regulatory requirements and updated guidelines. JCR maintains such currency.

A.3. We are seeking public comment related to whether commenters perceive a conflict of interest in AOs providing fee-based consulting services to the facilities they accredit.

The Joint Commission AO does not provide fee-based consulting services to the facilities it accredits. The Joint Commission supports the position that to do so presents a real or perceived conflict of interest. Any enterprise that provides accreditation services and fee-based consultative technical assistance must do so only with the establishment of separate corporations that are constructed to have and maintain the same rigorous Firewall policies that have been successfully implemented by The Joint Commission enterprise.

The Joint Commission upholds and continually reviews its Firewall Policy and related processes (See also Sections A.1. and A.6. for additional specific details of the Firewall policy) and is therefore confident that there should be no actual or perceived conflict of interest between accreditation and the consulting services provided by JCR.

A firewall has been in place since 1987 and has been enhanced over the years to remain up to date with the structure and operations of the organizations. What has never changed is the core principle addressed by the policy – to protect the integrity of The Joint Commission accreditation process. The policy was tested by GAO investigators in 2006, with a final report issued December 2006 that concluded:

“Despite The Joint Commission’s control over JCR, the two organizations have taken steps designed to protect facility-specific information. In 1987, the organizations created a Firewall—policies designed to establish a barrier between the organizations to prevent improper sharing of this information. For example, the Firewall is intended to prevent JCR from sharing the names of hospital clients with The Joint Commission. Beginning in 2003, both organizations began taking steps intended to strengthen this Firewall, such as enhancing monitoring of compliance.

Ensuring the independence of The Joint Commission’s accreditation process is vitally important. To prevent the improper sharing of facility-specific information, it would be prudent for The Joint Commission and JCR to continue to assess the Firewall and other related mechanisms.”

The Joint Commission Enterprise Firewall Policy is designed to protect the integrity of the accreditation process. The policy and accompanying procedures govern staff behavior to ensure independence in the survey process. Staff are directed in maintaining the strict confidentiality of any information related to consulting and accreditation. Thus, JCR staff cannot provide Joint Commission accreditation staff with any organization–specific information obtained during a consulting engagement, including the name of an organization receiving such services. Likewise, Joint Commission accreditation staff cannot provide any confidential accreditation information to JCR consulting staff. In this manner, all decisions related to Joint Commission accreditation are made without any “insider” knowledge of which organizations are receiving consulting services and are made without bias.

The Firewall Policy is a board-approved policy with oversight by the Enterprise Audit and Firewall Oversight Committee of the Joint Commission Board of Commissioners. It is this Committee that tests compliance with the policy on a biennially and approves any recommended changes to the policy. Application of the policy is monitored by The Joint Commission’s Corporate Compliance and Privacy Officer, who ensures that any risks to policy compliance are immediately and fully addressed by the senior leadership team, and answers questions related to the policy. All staff are trained on and expected to adhere to the policy and have routine access to the compliance program to provide answers to any questions that may arise. The Firewall Policy is tested on a regular basis to ensure compliance.

A.4. We are seeking public comment related to some stakeholders' perception that the ability of an AO to collect fees for consultation services from entities they accredit could degrade the public trust inherent in an AO's CMS-approved accreditation programs.

The Joint Commission takes the public trust in its accreditation programs very seriously. As mentioned, consultative technical assistance services are provided by JCR, a separate affiliated entity. There is no organizational, staff, or data system overlap between JCR consultative technical assistance services and Joint Commission accreditation, and a strict Firewall and related policies are in place and continuously monitored to eliminate any perceived or actual conflicts of interest.

A.5. We are seeking public comment on what the appropriate consequences or impacts should be, if a conflict does exist.

Any AO that has an affiliation with a consulting entity or any AO that is considering establishing a consulting entity should ensure that a strong Firewall and related processes are developed to avoid potential and actual conflicts of interest. Should an AO have a confirmed conflict of interest arise due to the provision of consulting services that resulted in an accreditation decision favorable to the facility, CMS should consider action against both the AO and its deeming authority and the facility's accreditation and deemed status.

A.6. We are seeking public comment on what Firewalls may exist within an AO between accreditation and consultation services, or what Firewalls would be prudent, to avoid potential and actual conflicts of interest.

Firewall policy and procedure development and implementation are not simply prudent—they are necessary to avoid any conflict of interest between the AO and the consulting entity. The Joint Commission has established a strong and heavily enforced Firewall policy (Also see A.1. above). The Joint Commission Enterprise Audit and Firewall Oversight Committee of the Joint Commission Board is tasked with the charge "...to take all steps necessary to preserve the utmost integrity of the accreditation process of The Joint Commission." This committee ensures that consultative technical services offered by JCR do not jeopardize the integrity of the accreditation process of The Joint Commission. The Committee does this by:

- Reviewing and approving all policies and documents related to the Firewall.
- Providing advice to the President and CEO on Firewall Policy implementation and making recommendations for enhancing the policy.

- Determining when to conduct the periodic review and testing of the policy, receive the reports and share with the entire Board.
- Receiving reports from the Corporate Compliance and Privacy Officer on the status of the Firewall.

The Firewall Policy, to prevent any real or perceived conflict of interest with consulting services provided by JCR, prescribes a wide array of specific organizational practices that are outlined in Section A.1. above. These practices include a number of limitations (see section A.1.) on JCR consultants that, by design, disadvantage them compared to other consultants with whom they compete. For example, JCR consultants must immediately leave a health care facility if Joint Commission surveyors arrive to conduct an unannounced accreditation survey. Collectively, these restrictions serve to underscore the vigor with which the Joint Commission enterprise acts to protect the integrity of its accreditation processes by eliminating the appearance or reality of conflicts of interest between its accreditation and consulting functions.

Enhancements of the policy through the years include the hiring of a Joint Commission enterprise Corporate Compliance and Privacy Officer (CCPO) with responsibility for the application of the Firewall Policy and related policies, and providing regular reports to the President and the Board-level Audit and Firewall Oversight Committee; The Joint Commission's institution of a full compliance program, which includes a Compliance Council that along with the CCPO provides operational direction for adherence to the Firewall policies; training on the Firewall Policy and related policies provided to every new Board member and employee at orientation and periodically thereafter based on their roles within the organization; and establishment of a compliance line and anonymous hotline to receive reports or questions from staff.

With commitment to ensuring public trust, The Joint Commission AO and JCR each take adherence to the Firewall very seriously. External evaluations and monitors are performed biennially, with internal audits in the alternate years. Audits inform procedural changes or training necessary to ensure compliance to the policies.

A.7. We are soliciting examples of positive and negative effects which may be a result of a conflict of interest.

It is important to understand why The Joint Commission enterprise supported creation of a separate legal entity to offer consultative technical assistance services to healthcare organizations. Many consultants were offering such services and it was not uncommon for Joint Commission AO surveyors, upon identifying a standard that was out of compliance, to hear protests from organizations that a consultant told them that the practice in question was fully compliant with Joint Commission standards when that was not indeed true. The Joint Commission believed that a consulting organization affiliated with but separate from The Joint



Commission as an AO, could provide more accurate and expert advice on standards compliance.

As mentioned earlier, JCR has highly trained staff who are experts in the field of quality and patient safety. These consultants understand both the accreditation process and quality improvement. Their unique knowledge gives JCR's customers the skills they need to improve patient safety and quality care. JCR's consultative technical assistance services have improved the quality of care delivered by its customers.

There are risks of a conflict of interest when any AO considers providing accreditation-related consulting. However, The Joint Commission's 30-year track record has demonstrated that appropriate and effective policies and procedures prevent both the perception and reality of conflicts that might jeopardize the integrity of the accreditation process. The benefits of safer, higher quality patient care considerably outweigh the small, residual perception of potential risk, particularly when such risks are mitigated by a robust Firewall compliance program such as the one The Joint Commission has established. In fact, the GAO completed a separate analysis on health care organizations' perception of conflict of interest. After calling on individual organizations to hear their impressions, no perceptions of conflict were reported. The analysis released January 12, 2007, concluded:

"The Joint Commission has taken steps to avoid improper information sharing."

A.8. We are seeking public comment from existing AOs on what the potential impact, financially and overall would be if CMS were to finalize rulemaking which would restrict certain activities that might give rise to a real or perceived conflict of interest.

Significant restrictions on JCR's ability to conduct accreditation-related consulting despite the safeguards described herein would significantly impair the ability of The Joint Commission and JCR to carry out their missions. The magnitude of the impacts would depend on the precise nature of the restrictions that any future regulations would define. Because these are unknown at present, the impacts on the missions, operations, and finances of the two companies cannot be estimated.

A.9. We are seeking public comment, primarily from stakeholders, by requesting specific information on when and/or under what circumstances it would be appropriate for AOs to provide fee-based consulting services to the facilities which they accredit.

Any AO that has an affiliation with a consulting entity or that is considering establishing a consulting entity must ensure the consulting entity is a separate component of its organization, with established, independently reviewed, and rigorous Firewall policies consistent with the ones that have been successfully tested by The Joint Commission enterprise. Related processes and frequent staff training must be in place to avoid potential and actual conflicts of interest. Given the structures and processes implemented within The Joint Commission enterprise to maintain the integrity of the accreditation process (as described in detail in the sections above), it is entirely appropriate for JCR to provide consultative technical assistance services to healthcare organizations clients in order to help them improve the quality of the care they deliver.

A.10. We are seeking public and stakeholder feedback on whether, and if so, under what specific circumstances CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.

CMS should implement a complaint process and review all complaints regarding a potential conflict of interest in an AO. The complaint process should include a determination that the organization has developed and implemented Firewall policies and procedures and regularly audits their effectiveness.

A.11. Specifically, we are seeking comments in a list type format describing under what circumstances the AOs or stakeholders would believe there to be a conflict; and under which circumstances conflict does not exist.

Some examples are listed below. All of these examples are addressed in the existing Firewall Policy and related policies and procedures of The Joint Commission enterprise.

ISSUE	CONFLICT	NO CONFLICT
Consultant prepared an organization for accreditation and shared information with accreditation staff.	X	
Consultant remained involved with the organization during accreditation survey or decision process	X	
AO shared organization-specific identifying information or any findings with consulting resulting in generating consulting business	X	
Consulting and accreditation jointly providing non-standard specific education		X

A.12. We seek comment on the type of information which would be considered necessary, useful and/or appropriate in proving or refuting our hypothesis of a connection between the use of consulting services and the preferential treatment of accredited providers and suppliers. We are seeking comment on alternatives for addressing any conflict of interest identified.

As detailed above, in the case of The Joint Commission, much evidence confirms that JCR consultative technical assistance services do not confer any preferential advantage to its customers in the Joint Commission accreditation process.

It is recommended that the following questions be answered to determine if there is an appropriate relationship between AOs and any affiliated consulting entities.

1. Is the consulting organization separated organizationally from the accreditation organization; specifically, is it a different corporation?
2. What protections exist to ensure that no organization-specific information (including any names or identifiers of client organizations) is shared between consulting personnel and accreditation personnel or vice versa; how these are enforced?
3. What policies and processes are in place to address any and all perceived or actual conflicts of interest?
4. How are such policies and processes reviewed, tested, updated, and implemented, including training and resources to all staff? How frequently are these reviewed internally and by an independent external entity? How are deficiencies found by external auditors addressed?
5. Is there a compliance officer, and a compliance program which monitors the process for receiving staff concerns about potential Firewall issues?
6. Does the Firewall policy, process, and compliance program have senior-level attention from the most senior management and the Board?

Strong evidence related to refuting the hypothesis of a connection between the use of consulting services and preferential treatment of accredited providers and suppliers relative to The Joint Commission enterprise is found in the January 2007 Government Accountability Office report examining the relationship of The Joint Commission AO and JCR. This report examined both real and perceived conflicts of interest.

B. Financial Impact and Burden

B.1. We are seeking public comment regarding how an AO's revenue and operations may be affected by a prohibition or limitation on AO's marketing and provision of consulting services.

Significant restrictions on JCR's ability to conduct accreditation-related consulting despite the safeguards described herein would significantly impair the ability of The Joint Commission and JCR to carry out their missions. The magnitude of the impacts would depend on the precise nature of the restrictions that any future regulations would define. Because these are unknown at present, the impacts on the missions, operations, and finances of the two companies cannot be estimated.

As not-for-profit organizations, financial information about The Joint Commission and JCR is available on their public websites.

C. Adding a new CFR Subpart to Existing Regulation

C.1. We are seeking stakeholder feedback on the most appropriate area for this potential future rulemaking under the existing regulations for AOs and whether expanding 488.5 (a) (10) to include a provision addressing this matter would be the most sensible placement.

As mentioned in the RFI, 488.5(a)(10) currently requires that an AO submitting an application must include a copy of the “organization’s policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.” It would be appropriate for CMS to use this section of the federal code to ensure that applications for deeming authority underneath this section include documentation that the organization has developed, implemented, and routinely audited Firewall policies and procedures. The questions identified in A.12 can assist them in making determinations.