

## **Guidance From Staff of the Bureau of Competition’s Health Care Division on Requesting and Obtaining an Advisory Opinion\***

The Federal Trade Commission’s Rules of Practice provide that the Commission or its staff, in appropriate circumstances, may offer industry guidance in the form of an advisory opinion. Advisory opinions serve a public informational and educational function, in addition to their value to the opinion requesters. The basic requirements for obtaining advisory opinions; the limitations on their issuance and application; and the point at which both a request for an advisory opinion and the advisory opinion will be placed on the public record are in [Sections 1.1 – 1.4 of the Commission’s Rules of Practice](#), 16 C.F.R. §§ 1.1-1.4. These requirements and limitations, as well as practice tips for requesting an FTC advisory opinion, are described in greater detail below.

In recent years, the staff of the Bureau of Competition has issued numerous advisory opinions on a variety of proposed activities and arrangements in the health care area. If you are considering making a request for an advisory opinion, consider the practical guidance below, which is based primarily on staff’s experience with advisory opinion requests concerning competition issues arising in the health care area. This guidance, which is consistent with the Commission’s rules and procedures for requesting an advisory opinion on any topic that is subject to the Commission’s jurisdiction, also may be useful if you are seeking an advisory opinion in areas other than competition and health care.

### **What Are the Types of Advisory Opinions?**

There are two types of advisory opinions: (1) Commission advisory opinions, and (2) advisory opinions provided by the Commission staff.

Requests for a Commission advisory opinion will be considered where: (1) the matter involves a substantial or novel question of fact or law and there is no clear Commission or court precedent; or (2) the subject matter of the request and consequent publication of Commission advice is of significant public interest. A request suitable for a Commission advisory opinion will be considered -- and the Commission will respond by providing an advisory opinion -- “where practicable.” Where a request does not meet the requirements for a Commission opinion, or where a Commission opinion is otherwise not practicable, the Commission has authorized the FTC staff to consider the request and to render advice, “where practicable.”

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\* The information and views provided in this document reflect the experience of the Bureau of Competition staff in dealing with advisory opinion requests, and are intended as informal guidance to those who may be considering filing a request for an advisory opinion. This guidance has not been approved or adopted by the Federal Trade Commission and does not necessarily represent the views of the Commission or any individual Commissioner.

**Practice tip:** Most advisory opinions are issued by FTC staff, rather than by the Commission, even if a Commission opinion is requested.

The Department of Justice also offers opinions regarding certain conduct through its program of issuing business review letters. Information on that program can be found at 28 C.F.R. § 50.6, and on the website of the Antitrust Division of the Department of Justice, at <http://www.justice.gov/atr/business-reviews>.

### **Who May Request an Advisory Opinion?**

Commission Rule 1.1(a) provides that any person, partnership, or corporation may request an advisory opinion regarding **proposed conduct** that is a proper subject for an opinion (see discussion below). This requirement conforms to the delineation of Commission jurisdiction that appears in Section 5(a)(2) of the Federal Trade Commission Act. Consequently, an entity that is not subject to the Commission's jurisdiction may not request an advisory opinion. For example, for this reason, requests for an advisory opinion involving agreements or joint conduct between or among certain non-profit entities that are not subject to the Commission's jurisdiction have been referred to the Department of Justice as possible candidates for business review letters.

More generally, the Commission and the Department of Justice maintain a clearance procedure regarding requests for advisory opinions and business review letters, in order to assure that the more appropriate agency handles a given request, based on factors such as jurisdiction or familiarity with a particular industry.

**Practice tip:** If you are uncertain about whether you can request an advisory opinion, contact FTC staff to discuss the matter before filing a formal request for an advisory opinion.

### **What Are Proper Subjects for an Advisory Opinion?**

Not all requests for an advisory opinion will be considered by the Commission or the FTC staff. Commission Rule 1.1(a) provides that a request for an advisory opinion must concern a course of action that the requesting party proposes to pursue. Specifically, the requesting party or parties must intend to engage in the proposed conduct; hypothetical questions or questions regarding conduct that is already ongoing will not be answered. Consequently, a proposed course of action must be sufficiently developed for the Commission or the FTC staff to conclude that it is an actual proposal, not a mere possibility, in order to evaluate the proposal based on the description and supporting information provided with the request. At the same time, the course of action at issue must not yet have been undertaken.

Commission Rule 1.1(b) provides that a request for an advisory opinion will ordinarily be considered inappropriate where: (1) the same or substantially the same course of action is under investigation; (2) the same or essentially the same course of action is or has been the subject of a current proceeding involving the Commission or another governmental agency; or (3) an informed opinion cannot be made, or could only be made after extensive investigation, clinical study, testing, or collateral inquiry.

Regarding point (3), a request for an opinion will only be considered where the Commission or FTC staff can reliably reach an informed conclusion regarding the proposed conduct based on the information submitted by the requester, without having to pursue an independent investigation or undertake an extensive market or technical analysis. The staff does not routinely seek to verify information provided by an applicant in support of a request, or request information from third parties, although the staff may occasionally ask outside parties to provide relevant information on a voluntary basis. FTC staff cannot compel cooperation from third parties regarding advisory opinions, and may not be able to obtain necessary or complete information from outside sources. Thus, the information submitted in support of an advisory opinion request must itself be sufficient to support any assertions by the requester regarding the proposal.

**Practice tip:** In competition matters, a request for an advisory opinion generally is best suited to situations where the important market facts are fairly clear and the legality of the conduct at issue is unlikely to turn on an analysis of market power. By contrast, where complex factual issues such as market definition make it difficult to predict the likely competitive effects of the proposed conduct, the process is less likely to produce a definitive opinion, assuming that one can be issued at all. For example, an advisory opinion request concerning a proposed merger or acquisition is unlikely to be appropriate for, or result in the issuance of, an advisory opinion, except in rare circumstances (such as hospital mergers that may fall within the “safety zone” for certain small hospital mergers in Statement 1 of the Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and the Department of Justice, and available at [https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements\\_of\\_antitrust\\_enforcement\\_policy\\_in\\_health\\_care\\_august\\_1996.pdf](https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf)). Even if it cannot be determined whether a proposal would be lawful under a rule-of-reason analysis involving market definition and the assessment of competitive effects, it may be possible to render an opinion as to whether the proposed conduct involves activity that would be considered *per se* illegal.

The Commission’s rules provide no limitations on the industries or subject areas for proposed activity that may be considered for an advisory opinion. In practice, however, the majority of advisory opinions have related to the health-care sector. Since 1982, the agency has issued more than 100 advisory opinions regarding proposed activity in the health-care sector. Of these, nine have been Commission advisory opinions, and the remainder have been issued by the FTC staff. Particular areas of interest for requesters of health-care advisory opinions have included

physician and other health-care provider network joint ventures; the collection, exchange, and provision of information, including price information, among health care providers; the provision of information by providers to purchasers and payers; professional society activities; and the applicability of the Non-Profit Institutions Act exemption from the Robinson-Patman Act to certain purchases and uses of pharmaceuticals. Other opinions have addressed joint purchasing arrangements; “messenger model” arrangements for dealings between health-care providers and payers; and non-network joint ventures. An index of all Commission advisory opinions can be found at <https://www.ftc.gov/policy/advisory-opinions>. Advisory opinions related to health care issues can be found at [https://www.ftc.gov/policy/advisory-opinions?title&term\\_node\\_tid\\_depth=3517](https://www.ftc.gov/policy/advisory-opinions?title&term_node_tid_depth=3517).

One important limitation on advisory opinion requests, as noted above, is that they must relate to future conduct; they cannot address conduct that has already begun. If a request details ongoing conduct that raises competitive issues, the agency will refuse to consider the request and instead may open a law enforcement investigation into the ongoing conduct.

In some instances, a proposed course of conduct may involve an entity already in operation that plans to undertake a new program or activities, and seeks an opinion regarding its future operations. As long as the program or activities about which the request seeks an opinion are not already a part of the applicant’s ongoing operations, they may be a proper subject for the issuance of an advisory opinion. Applicants should be certain to explain how the proposed course of conduct differs from the practices already being used. This type of situation has arisen, for example, where a physician or health-care provider network joint venture already provides certain services in a given market, and now seeks to implement a new program that is not already present in the network’s current operations and in which its competing members would agree on the terms of dealing, such as price terms, to be negotiated with payers. Thus, for example, a provider network that already provides credentialing, utilization management, medical or case management, peer review, or other services may properly seek an advisory opinion regarding a proposed program to jointly offer its members services under a financially or clinically integrated arrangement.

Similarly, a network may currently jointly contract with payers on behalf of its members under arrangements that involve significant integration through the sharing of substantial financial risk by the participants. That situation would not preclude the network from seeking an advisory opinion regarding a new proposal (for instance, to jointly offer services and contract for a clinical integration program) as long as the justification for that agreement does not rely on the participants’ pre-existing financial integration. Nevertheless, the overall proposed program could incorporate previously operational activities not involving the proposed arrangement without necessarily disqualifying an opinion request.

### **What Conduct May an Applicant Undertake Prior to Issuance of an Advisory Opinion?**

As previously noted, advisory opinions are limited to proposed conduct, and will not be issued regarding ongoing conduct. In addition, a proposed course of conduct for which an advisory opinion is sought must be sufficiently concrete and detailed so as to be more than hypothetical, and to allow for an in-depth evaluation of the proposal. Nonetheless, it sometimes may be reasonably necessary for requesters of an advisory opinion, prior to issuance of the opinion, to undertake certain preparations and activities not directly involving the specific competitive restraint about which an opinion is sought. This may be necessary in order to effectively organize participants and establish the overall arrangement, ascertain its market viability, and assure its timely and effective implementation, should it receive a favorable opinion. For example, in the health-care sector, in order to assure that a proposed program will be something that payers are likely to find valuable and for which they potentially may be willing to contract, a physician or other health-care provider network joint venture may reasonably need to discuss the program's proposed structure and method of operation, capabilities, and goals with payers before submitting a request for an opinion. Similarly, while an advisory opinion request is under consideration by the Commission or FTC staff, some discussions with potential customers about future implementation of a proposed program may be reasonably necessary to the program's effective and timely implementation after an opinion has been issued. As long as the pre-opinion conduct does not include actual joint agreement by competing network participants on prices or other competitively significant terms of dealing that otherwise would be decided individually by the participants, and does not involve collective negotiation or agreement with payers, such pre-operational activity is unlikely to jeopardize an advisory opinion request.

### **How Do I Request an Advisory Opinion?**

To formally request an advisory opinion, file the request with the Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 135-H, Washington, D.C. 20580, in the manner prescribed by Commission Rule 4.2(d)(1). The request should include one original, plus two paper copies, and an electronic copy on CD or DVD. For a request concerning health-care antitrust and competition issues, also send two additional copies directly to the Assistant Director, Health Care Division, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. There is no fee for filing an advisory opinion request or receiving an advisory opinion.

Commission Rule 1.2 requires requests for advisory opinions to state clearly the questions or issues about which the applicant seeks an advisory opinion, identify the provisions of law under which the request arises, and include all facts and supporting information that the applicant believes to be material to resolution of the matter.

If confidential treatment is requested for the advisory opinion request, a redacted public version should be filed at the same time, so that it can be placed on the public record at the same time as the resultant Commission or FTC staff advisory opinion, as prescribed by Commission Rule 1.4.

A request for confidential treatment must conform to the requirements of Commission Rule 4.9(c), as discussed in more detail below.

**Practice tip:** Parties also may obtain less formal advice regarding a proposed course of action by contacting FTC staff to discuss issues relating to proposed conduct. Previous applicants for advisory opinions, particularly those involving complex issues in the health-care area, often have found it helpful to discuss potential requests with staff prior to formally filing the requests. Such prior discussion, either in person or by telephone, may help a potential applicant decide whether it is appropriate or worthwhile to proceed with a request, facilitate formulation of an appropriate request, and help clarify what information needs to be provided in support of a given request. Similarly, upon request, the staff may be willing to review a draft of an advisory opinion request prior to its formal submission. These activities, in turn, may help expedite the agency's handling of, and response to, the request, once it is formally submitted.

### **What Materials Should I Submit in Support of My Advisory Opinion Request?**

In addition to identifying the companies or other persons involved in the proposed course of action, Commission Rule 1.2 requires an advisory opinion request to state all facts that the applicant believes to be material. The information that is material to a particular request obviously will vary depending on the subject of the request and the factual setting and circumstances in which the proposed course of action will occur or operate. Advisory opinions generally state that they are premised on the facts and circumstances as represented by the requester in the request and any supplemental submissions, and as those facts are understood by the Commission or the staff. As discussed below, material differences between a proposal's description and its actual subsequent operation likely will render an advisory opinion inoperative.

A request for an advisory opinion also should include a complete description of the proposed activity or venture, including who will participate in it, what the requester proposes to do, and how it will operate. This may include discussion of any expected or likely procompetitive, efficiency-enhancing, or consumer-benefitting aspects of the proposed venture, and how those benefits will be ascertained and measured. Since any proposed activity for which an advisory opinion is sought likely involves some elimination of competition among the participants, this aspect of the proposal should be fully and candidly addressed in the request. Common questions likely to be asked by staff include:

- Why is the proposed activity being undertaken?
- Why is the proposed activity structured and proposed to operate in the particular manner described?

- Why couldn't the proposal be structured and operate in a competitively less restrictive manner – i.e., without involving the competitive restraints that prompted the request for an advisory opinion?

A description of the environment in which the proposed arrangement will operate, including potential customers, competitors, market alternatives, or other aspects of the market, also will be helpful in evaluating a proposal.

**Practice tips:** (1) Be candid and forthcoming about all aspects of the proposal, including areas of uncertainty and potential negative effects on competition. Acknowledgment of uncertainties or the absence of certain information will not necessarily preclude issuance of an opinion. A lack of candor may undermine the credibility of the requester with staff, and ultimately could limit any opinion that may be rendered or even lead to the rejection of the request.

(2) Provide as much detail as practicable about the proposed program to facilitate the review. Under the Commission's rules, the staff can, and frequently does, ask the party requesting an advisory opinion to provide additional information that staff considers necessary in order to evaluate the request and potentially render an opinion.

(3) Ensure that the participants in a proposed program, and not merely their legal counsel, have had significant involvement in planning the program and preparing the advisory opinion request, so that the request discusses the proposal in practical, real-world, terms. This is especially important if the participants want agency staff to fully understand and appreciate the benefits of the proposed arrangement and the need for the competitive restraint that is the focus of the advisory opinion request. In developing a proposal, it is advisable for the parties who actually will manage or operate the proposed program to focus primarily on what the market demands, rather than on what the requester's counsel believes will result in a favorable advisory opinion. A proposal that responds to real market demands is likely both to be a better product, and to provide a better basis for asserting that it is procompetitive and lawful.

(4) Review advisory opinions previously issued by the Commission or FTC staff regarding similar types of conduct or arrangements. These opinions may provide guidance as to the types of factual and legal questions that certain types of conduct are likely to raise, as well as the types of information to be submitted with a request that may be necessary or helpful in addressing those issues or questions.

### **How Long Will It Take to Obtain an Advisory Opinion?**

The length of time necessary to respond to a request for an advisory opinion will vary depending on several factors, including the nature and complexity of the issues posed by the proposed conduct, the magnitude and sufficiency of the request and supportive information provided with the initial request, the time it takes for the opinion requester to respond to any requests from staff for additional information, and whether the opinion will be issued by the Commission or the Commission staff, among other things. Some advisory opinions have been issued within a



matter of weeks after the request was filed, although it is more typical for opinions to take at least several months before the process is completed and an opinion is issued.

### **Can I Withdraw My Request for an Advisory Opinion?**

Requests by an applicant to withdraw a request for an advisory opinion prior to issuance of the opinion will be considered where that request is made relatively early in the process. Because Commission and FTC staff opinions also serve a public informational and educational function, a request to withdraw an advisory opinion request will not necessarily be honored. Copies of any withdrawn advisory opinion requests, including any supporting materials submitted with such requests, are maintained or destroyed in accordance with applicable Federal records retention laws and regulations. *See generally* Commission Rule 4.12 (16 C.F.R. § 4.12).

**Practice tips:** (1) A withdrawal request may be denied where (a) substantial time has passed since the initiation of an advisory opinion request, (b) substantial Commission resources have been expended in evaluating and preparing a response to the request, and (c) issuance of the opinion is considered to offer significant educational benefit to the industry and the public. Moreover, requests to withdraw an advisory opinion request generally will not be honored where the sole basis is the requester's belief or understanding that an unfavorable opinion is likely to be forthcoming.

(2) If the staff's request for additional information regarding a request is not adequately responded to within a reasonable period of time, FTC staff, on its own initiative, may deem the request to be withdrawn; if this happens, staff will notify the applicant. Involuntary withdrawal of a request generally is preceded by staff contacting the requester and informing the requester of the impending action. If a request is deemed withdrawn by the staff for failure by the requester to pursue it, the requester is free to file a new application for an advisory opinion whenever the requester is prepared to proceed with the process for seeking an opinion.

## **How Will I Be Notified that an Advisory Opinion Has Been Issued?**

FTC staff typically will notify an applicant shortly before issuance of an advisory opinion, so the requester can be prepared to address any media or other inquiries that may ensue from issuance of the opinion. The Commission typically announces the issuance of an advisory opinion in an FTC press release.

Once the applicant has been notified, the advisory opinion is placed on the public record of the Commission, as provided in Commission Rule 1.4 (16 C.F.R. § 1.4), typically at the same time as the FTC press release; both are placed on the Commission website at <https://www.ftc.gov/policy/advisory-opinions>. Commission advisory opinions also are published in the official FTC Reports, together with other official Commission actions and opinions.

## **What Information Will Be Publicly Disclosed and Can I Request Confidential Treatment of Information Relating to an Advisory Opinion Request?**

Commission Rule 1.2(a) requires the identity of the companies and other persons involved in a proposed course of action that is the subject of an advisory opinion request to be disclosed, and Commission Rule 1.4 provides that written advice and “requests therefor, including names and details” will be placed on the public record “immediately after the requesting party has received the advice.” Rule 4.9(b)(2) also states that the Commission’s public record includes Commission or staff advisory opinions.

The Commission’s rules also provide, however, that materials placed on the public record will be subject to any limitations on public disclosure arising from statutory restrictions, the Commission’s rules, and the public interest. Thus, an applicant is permitted to request confidential treatment of any information submitted in support of a request for an advisory opinion, in accordance with the requirements of Rule 4.9(c). Consistent with Section 6(f) of the FTC Act (15 U.S.C. § 46(f)), Rule 4.10(a)(2) identifies various categories of material that the Commission will consider to be nonpublic, including “[t]rade secrets and commercial or financial information obtained from a person and privileged or confidential . . . [including] competitively sensitive information,” several types of which are specified in the Rule.

Rule 4.9(c)(1) allows designation of submissions or portions of submissions as confidential and allows submitters to request that those materials be withheld from the public record. An advisory opinion request and any submitted documents that are considered confidential must be so marked at the time of submission. See Rule 4.2(b). Requesters also need to follow this same document marking procedure with regard to any confidential materials subsequently submitted in support of an advisory opinion request, for example when responding to a request from Commission staff for further information regarding the request. Pursuant to Rules 1.4 and 4.9(c), a requester seeking confidential treatment regarding an advisory opinion request also must inform the Secretary in writing, separately from the advisory opinion request, that the submitter is requesting confidential treatment of the materials marked as “confidential,” pending issuance of the advisory opinion.

The written request filed with the Secretary should be directed to the attention of the Commission's Office of the General Counsel, which ultimately will make the determination regarding the merits of the request for confidential treatment.

When it becomes clear that an advisory opinion is likely to be issued and subsequently placed on the public record, parties that initially designated an advisory opinion request or information and materials submitted in furtherance of that request as confidential will be afforded an opportunity to justify the confidentiality request "in light of applicable statutes, rules, orders of the Commission, . . . orders of the courts, or other relevant authority," as required by Rule 4.9(c)(1).

Rule 4.9(c) delegates to the General Counsel, or the General Counsel's designee, the responsibility to act on a confidentiality request "with due regard for legal constraints and the public interest." Where the confidentiality request is granted, the advisory opinion requester may be asked to provide a properly redacted copy of the request and materials for placement on the public record. If an applicant's request for confidential treatment is denied by the Office of the General Counsel, pursuant to Rule 4.9(c), and in accordance with Section 21(c) of the FTC Act, 15 U.S.C. § 57b-2(c), the applicant will be provided ten days' notice prior to the material being placed on the public record.

Trade secrets and commercial or financial information that is privileged or confidential also is exempt from disclosure under the Freedom of Information Act, 5 U.S.C. §552.

### **What is the Legal Effect of an Advisory Opinion?**

Advisory opinions (like Department of Justice business review letters) normally do not directly opine on the legality of the proposed conduct. Instead, a Commission advisory opinion will typically set forth the Commission's enforcement intentions regarding the proposed conduct, if it were to be undertaken. Similarly, an FTC staff advisory opinion will typically state whether the FTC staff would recommend that the Commission take law enforcement action to address the proposed conduct, if it were to be undertaken. Further, because advisory opinions are based on the information provided by the applicant, they are expressly conditioned on the accuracy and truth of the representations made by the applicant, as understood and summarized by the Commission or the FTC staff in the advisory opinion. Any material divergence of the actual situation from a requester's representations likely will render an advisory opinion inoperative.

The Commission issues an advisory opinion without prejudice to its right to reconsider the questions involved and, where the public interest so requires, to rescind or revoke the opinion. Notice of such a rescission or revocation will be given to the requester, so that he or she may stop any course of action undertaken in reliance on the Commission's prior advice. The Commission will not proceed against a requester with respect to any action taken in good faith reliance on the Commission's advice if all relevant facts were fully, completely, and accurately presented to the Commission, and where such action stopped upon notification that the Commission has rescinded or revoked the advice at issue.

Advisory opinions issued by the FTC staff are not formally approved by the Commission, and are without prejudice to the Commission's right to later rescind the advice and, where appropriate, to commence a law enforcement proceeding.

**Practice tip:** While they may have persuasive value, Commission and FTC staff advisory opinions are not binding on courts, other governmental entities, or private parties. Consequently, advisory opinions should not be considered to provide immunity from legal challenge by others to the conduct at issue, or from contrary or adverse legal determinations by courts or other decisional bodies.