

Podcast: Demystifying Agency Rulemaking, Ep. 2: Mastering Participation in the Process

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In the first part of our [two-part series](#) on agency rulemaking, we explored how the Administrative Procedures Act, the major questions doctrine, and the *Chevron* doctrine affect Federal agency rulemaking. In this part, we will explore the Paperwork Reduction Act, the Regulatory Flexibility Act, the Office of Information and Regulatory Affairs, and the importance of participating in the rulemaking process.

Douglas Charnas: Welcome to our podcast on Agency Rulemaking Part II. I'm Douglas Charnas, Member in McGlinchey's Washington, DC office. I practice corporate and tax law. I'm joined today by my colleagues Michael Blumenthal and David Waxman, who are both located in McGlinchey's Cleveland, Ohio office. Michael represents clients in environmental due diligence in real estate transactions, mergers and acquisitions, environmental compliance, permitting, and multimedia auditing. David represents clients on matters pertaining to real estate acquisition, development, redevelopment, construction, contracts and transactions, environmental compliance and insurance financing, opportunity zone transactions, leasing, and business acquisitions and divestitures.

David Waxman: Michael, in the first part of this two-part series on Federal agency rulemaking, we explored the role of the Administrative Procedures Act (APA), the Major questions doctrine, and the *Chevron* doctrine. Can you briefly review the Administrative Procedures Act?

Douglas Charnas: Michael and David, before we discuss these other procedural issues, I wanted to ask, when is the right time to focus on these issues? In the first part of the series, we talked about challenging an agency rule on the basis of whether the agency properly followed the Administrative Procedures Act. But is there something that we should be doing *before* the rule is finalized?

David Waxman: Absolutely. Businesses especially should take an active role in the rulemaking process. There are several times in the rulemaking process when businesses can comment. We're going to discuss when and what type of comments should be made. Let's start with a quick review of the Administrative Procedures Act.

The Administrative Procedures Act governs all three main Federal agency functions. One, rulemakings, two, adjudications, and three, licensing. The APA describes the rulemaking process with which agencies are required to comply. Typically, the agency must publish a notice of a proposed rulemaking and solicit and accept public comments on the rule.

Michael Blumenthal: Sure. The Administrative Procedures Act governs all three main Federal agency functions. One, rulemakings, two, adjudications, and three, licensing. The APA describes the rulemaking process with which agencies are required to comply. Typically, the agency must publish a notice of a proposed rulemaking and solicit and accept public comments on the rule.

David Waxman: Michael, would you say the notice of proposed rulemaking is the starting point for the public's involvement in an agency's rulemaking process?

Michael Blumenthal: I would say that it is the formal starting point, but it is not uncommon for businesses to provide an agency with comments before the proposed regulations are published. This is particularly the case when Congress passes a significant piece of legislation that requires agency rules to implement.

David Waxman: Doug, we know the APA is the centerpiece of agency rulemaking, but are there other laws that govern agency rulemaking?

Douglas Charnas: There are two major laws that govern Federal agency rulemaking in addition to the APA: the Paperwork Reduction Act (PRA) and the Regulatory Flexibility Act (RFA). The Paperwork Reduction Act, which was signed into law in 1980 and reauthorized in 1985, provides the statutory framework for the Federal Government's collection, use, and dissemination of information. It gives the Office of Management and Budget (OMB) authority over the collection of certain information by Federal agencies. The rules of the Paperwork Reduction Act include, or the goals, I should say, include minimizing paperwork and reporting burdens on the American public and ensuring the maximum possible utility of the information that is collected.

In support of these goals, the Paperwork Reduction Act requires Federal agencies to take specific steps before requiring or requesting information from the public. These steps include: one, seeking public comment on proposed information collections, and two, submitting proposed collections for review and approval by the Office of Management and Budget. Within OMB, the Office of Information and Regulatory Affairs (OIRA) carries out the information collection review.

It is easy to think in the abstract that information collected is going to be useful. It's another thing for an agency to be able to use the information collected. Does it have the technical capacity and personnel resources to store and retrieve all the information proposed to be collected and use it for the intended purpose? An agency should be able to demonstrate its ability to do so before imposing the paperwork burden on the business. Can it accomplish its intended purpose by collecting less than all the information it proposes to collect? These are issues to explore during the rulemaking process.

David Waxman: Okay, so if I understand this correctly, when a Federal agency publishes a notice of proposed rulemaking, the notice should solicit comments from the public and the proposed collection of information.

Michael Blumenthal: I think it's important to note here that the paperwork burden imposed by proposed regulations may be as problematic for businesses as the substantive rules being proposed.

Douglas Charnas: That's a great point, Michael. This presents an opportunity to challenge the proposed rules. Remember, the second goal of the Paperwork Reduction Act is to ensure the maximum possible utility from the information that is collected. It is easy to think in the abstract that information collected is going to be useful. It's another thing for an agency to be able to use the information collected. Does it have the technical capacity and personnel resources to store and retrieve all the information proposed to be collected and use it for the intended purpose? An agency should be able to demonstrate its ability to do so before imposing the paperwork burden on the business. Can it accomplish its intended purpose by collecting less than all the information it proposes to collect? These are issues to explore during the rulemaking process.

David Waxman: I'd like to discuss the role of the Office of Information and Regulatory Affairs, or OIRA, but before we get into it, I think we should talk about the role the Regulatory Flexibility Act (RFA) plays in rulemaking. Michael, could you address the RFA?

The RFA permits judicial review of agency compliance with certain provisions of the RFA, most importantly, the agency's certification of a rule's anticipated impact on small entities and its use of small entity definitions.

Michael Blumenthal: Yes, happy to do so. The RFA, which was enacted in 1980 and amended several times, requires agencies to consider the impact of the rules on small entities and to evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities when the rules *impose a significant economic impact on a substantial number of small entities*. Inherent in the RFA is Congress's desire to remove barriers to competition and encourage agencies to consider ways of tailoring regulations to the size of the regulated entities.

The Chief Counsel for Advocacy of the Small Business Administration (SBA) Office of Advocacy monitors agency compliance with the RFA and reports annually on the compliance to the President and certain Congressional committees. The SBA Office of Advocacy has issued a guide for government agencies on how to comply with the RFA.

Douglas Charnas: Michael, if I could interject, the RFA does not require that agencies necessarily minimize a rule's impact on small business if there are significant legal, policy, factual, or other reasons for the rules having such an impact. The RFA requires only that the agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory alternatives for reducing significant economic impact on a substantial number of such entities, and explain the reasons for their regulatory choices. Executive Order 13272, signed on August 13th, 2002, requires that agencies establish procedures and policies to promote compliance with the Regulatory Flexibility Act.

Michael Blumenthal: Precisely, but it's important to note that agencies do not have free rein in making these decisions. The RFA permits judicial review of agency compliance with certain provisions of the RFA, most

importantly, the agency's certification of a rule's anticipated impact on small entities and its use of small entity definitions.

When an agency begins a regulatory project, it must first decide if the rule will be subject to the RFA. The RFA applies to any rule that is subject to notice and comment procedures under the APA.

If the rule is subject to the RFA, the agency must then conduct sufficient analysis to measure and consider the regulatory impact of the rule and to determine whether there will be "a significant economic impact on a significant number of small entities." Both adverse impacts and beneficial impacts should be considered.

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If the agency certifies that there will be no significant economic impact on a substantial number of small entities, no further analysis is needed under the RFA. If the agency cannot certify that a rule will not have a significant impact on a substantial number of small entities, the RFA requires the preparation of an initial regulatory flexibility analysis (IRFA), which must be made available for public comments. The agency should publish the IRFA analysis or summary of it in the Federal Register with the notice of proposed rulemaking.

The IRFA must, one, describe the impact of the proposed rule on small entities, and two, describe any alternatives to the proposed rule that would minimize the impact while accomplishing the stated objectives of the applicable statutes. An analysis of the comments received on the proposed rule help determine whether the final rule will have a significant impact on a substantial number of small entities. If there is a significant impact, a final regulatory flexibility analysis must be prepared and be published with the final rule in the Federal Register.

Douglas Charnas: Michael, I recall hearing something about certain agencies being required to go through some additional steps with SBA. I'm pretty sure one of those agencies is the Environmental Protection Agency (EPA), and I know you know a lot about EPA.

Michael Blumenthal: Yes. And Doug, your recollection is correct. EPA, the Occupational Safety and Health Administration (OSHA), and the Consumer Financial Protection Bureau (CFPB) are subject to additional requirements. Before issuing rules subject to the RFA, agencies must notify the Chief Counsel for Advocacy of the SBA for possible comment. If the agency is EPA, OSHA, or the CFPB, the RFA requires the agency to hold small business advocacy review panels, which are a supplemental means for obtaining input on the proposed rule and IRFA.

One of the most significant requirements of the Executive Order is that OIRA must review all significant regulatory actions before the actions take effect. It also assigns OIRA the responsibility of coordinating Inter-Agency Executive Branch review of significant regulations before publication.

Within 15 days of receiving that notification from these three agencies, the Chief Counsel is to identify the individuals that are representative of affected small entities. The agency is then to convene a review panel for the rule consisting of employees from the Rulemaking agency, the Office of Management and Budget, Office of Information and Regulatory Affairs, and SBA's Chief Counsel for Advocacy. The panel is to review rule-relevant

materials the agency has collected pertaining to the rule's anticipated impacts on small entities and collect advice and recommendations of the small entity representatives on issues related to components of the IRFA. Within 60 days, the panel is to report on the comments it received and its findings to make the report public as part of the rulemaking record. The RFA then directs the agency to modify the proposed rule and the IRFA as appropriate.

Douglas Charnas: Well, this is a lot of behind the scenes work that most people do not know is happening. If you are looking to challenge a rule issued by one of these three agencies, the convening of the review panel is one more of the items to check to make sure it was done. David, now that we have covered the Paperwork Reduction Act and the Regulatory Flexibility Act, I think we can circle back and talk about the role of OIRA in rulemaking. Is it fair to say that it is through OIRA that the White House plays its role in the rulemaking process?

David Waxman: Yes, that's a fair statement. As we noted earlier, OIRA is part of OMB, and OMB is part of the Executive Office of the President.

OIRA was established in the 1980 Paperwork Reduction Act. It reviews government collections of information from the public under the Paperwork Reduction Act, reviews draft proposed and final regulations under Executive Order 12866, and develops and oversees the implementation of government-wide policies in the areas of information policy, privacy, and statistical policy. It also oversees agency implementation of the Information Quality Act, including the peer review practices of Agencies.

Executive Order 12866, titled "Regulatory Planning and Review," issued by President Clinton establishes and governs the process under which OIRA reviews Agency draft and proposed final regulatory actions. The objectives of the Executive Order are to enhance planning and coordination with respect to both new and existing regulations, to reaffirm the primacy of Federal agencies in the regulatory decision making process, to restore the integrity and legitimacy of regulatory review and oversight, and to make the process more accessible and open to the public.

Don't wait for EPA to issue proposed regulations. Decide who at EPA is going to have responsibility for developing the rules and open a dialogue. Identify issues and raise them with EPA. Provide comments to EPA while it's developing the proposed rules and request a meeting to discuss the issues.

One of the most significant requirements of the Executive Order is that OIRA must review all significant regulatory actions before the actions take effect. It also assigns OIRA the responsibility of coordinating Inter-Agency Executive Branch review of significant regulations before publication.

Douglas Charnas: David, can I interject here? I wanted to note that on June 9th of this year, Treasury and OMB agreed that tax regulatory actions will no longer be subject to OIRA review. Historically, tax regulations generally were not subject to OIRA review, but in 2018, Treasury and OMB agreed that tax regulations would receive OIRA review if they likely interfered with actions planned or taken by other Federal agencies, raised new legal or policy issues, or had an annual non-revenue economic impact of at least \$100 million.

David Waxman: On January 18th, 2011, President Obama issued Executive Order 13563, which emphasizes the importance of protecting “public health, safety and our environment while promoting economic growth, innovation, competitiveness, and job creation.”

Douglas Charnas: These are a lot of hurdles for agencies to clear when promulgating rules. The Administrative Procedures Act generally requires agencies to follow the notice and comment procedure. The Paperwork Reduction Act requires agencies to take specific steps before requiring or requesting information from the public. The Regulatory Flexibility Act requires agencies to consider the impact of their rules on small entities and to evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities when the rules impose a significant economic impact on a substantial number of small entities. And Executive Orders add some additional requirements.

Failure of an agency to follow any one of these requirements could cause the agency rule to be held invalid. The process of promulgating agency rules provides a number of safeguards for individuals and businesses subject to these agency rules, and that it is up to the individuals and businesses to ensure that the agencies observe these safeguards. So how does this all play out in the real world?

OIRA’s policy is to meet with any party interested in discussing issues on a rule under review, whether they’re from state or local governments, small business or other business interests, or from the environmental, health, or safety communities. Under OIRA procedures as set forth in Executive Order 12866, meetings on regulatory actions must be conducted by the OIRA Administrator or a specific designee.

Michael Blumenthal: Let’s assume Congress enacts law that is designed to protect the environment. It is clear from the statute that EPA is going to have to provide rules to implement the new legislation. It is also likely that EPA rules will impose a significant economic impact on a substantial number of small entities, and that you happen to be a small entity. What do you do?

Douglas Charnas: Well, my immediate reaction is to hire an experienced EPA lawyer.

Michael Blumenthal: Yes, it’s always a good move to hire me, but what guidance should I be giving you?

David Waxman: Be proactive. Don’t wait for EPA to issue proposed regulations. Decide who at EPA is going to have responsibility for developing the rules and open a dialogue. Identify issues and raise them with EPA. Provide comments to EPA while it’s developing the proposed rules and request a meeting to discuss the issues.

Michael Blumenthal: Exactly, all of those actions are important. A key to successfully working with any agency is to understand the agency’s process. How does it go about addressing issues in its rules? Understand what it can and cannot do under the statute. If there is a particular result you want, show the agency how it can achieve that result in its rule under the statutory authority.

Douglas Charnas: David, I understand that you can monitor the OIRA docket to see when the agency sends a proposed rule to OIRA for review. So in our example for an EPA rule, you would know when OIRA has the rule under review. I think that’s correct. Is there an opportunity to meet with OIRA to discuss the Rule?

David Waxman: OIRA's policy is to meet with any party interested in discussing issues on a rule under review, whether they're from state or local governments, small business or other business interests, or from the environmental, health, or safety communities. Under OIRA procedures as set forth in Executive Order 12866, meetings on regulatory actions must be conducted by the OIRA Administrator or a specific designee. A log, available on [reginfo.gov](https://www.reginfo.gov), that's [reginfo.gov](https://www.reginfo.gov), is kept of those meetings.

Douglas Charnas: So even before a rule is published as a proposed regulation, you have two bites at the apple. You can comment to the agency, EPA in our example, while it is developing the rule, and then comment to OIRA once it has the rule under review. I suspect many businesses are not aware that they can get involved this early in the process,

David Waxman: And I suspect you're right. Of course, once the proposed regulations are published in the Federal Register, the official comment period begins. Any comments submitted are part of the official record and then open to the public for review.

Once the proposed regulations are published in the Federal Register, the official comment period begins. Any comments submitted are part of the official record and then open to the public for review.

When commenting on proposed regulations, remember to consider the Paperwork Reduction Act and Regulatory Flexibility Act. Consider whether any information being requested is necessary, and if so, whether the method proposed for collecting that information is the best method. Would a collection of less information suffice? If you're a small entity, do the proposed rules impose a significant economic impact on you? If so, include this in your comments. Are there alternatives you can propose that would accomplish the objectives of the rule without unduly burdening you?

Michael Blumenthal: Absolutely, while we tend to focus on the substance of the rules being proposed, these procedural aspects of information being requested and the burdens being imposed are of equal importance. As noted earlier, it is not uncommon for the administrative cost of complying with the paperwork requirements to exceed the cost of complying with the substantive aspects of the rule.

Douglas Charnas: Michael and David, thank you for all this important information on the rulemaking process. For me, the major takeaway is to be proactive. Let your voice be heard. Do not assume that someone else is going to address the issues that are important to your business. Agencies need feedback on their proposed rules and they generally welcome it. They know they cannot anticipate every way in which their rule may unduly burden a business or how their rule could accomplish its intended purpose in a less burdensome way. Be proactive.

Thank you for joining us today. McGlinchey lawyers work with many Federal and state agencies, and we would welcome the opportunity to address any regulatory issue you have.

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