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UNIVERSITY OF PENNSYLANIA LAW SCHOOL
SEMINAR ON
"OBAMA'S REGULATORY AGENDA:
A ONE-YEAR RETROSPECTIVE"

January 26, 2010

OIRA's Expansive Regulatory Authorities and the Need for Follow-Up of its Decisions

Abstract: *OIRA conducts two kinds of reviews: reviews of proposed regulations and reviews of information collections. Each review culminates in an OIRA decision. However, on occasion after those OIRA decisions are rendered new information or agency reluctance to abide by OMB's decisions demonstrate a need for ad hoc reviews of previous OMB decisions. In the past, OIRA has shown an unwillingness to revisit those decisions. I will present one example of each type of review during the first year of the Obama Administration that has raised an issue of whether and how to re-open or enforce a former OIRA decision. The first example involves E.O. 12866 review of the requirements for supplying durable medical equipment under Medicare. The second example involves OIRA review of the EPA test requirements for the Endocrine Disruptor Screening Program under its paperwork review authority. I will then present some recommendations.*

Unlike Federal departments and agencies, which are not a Constitutional branch of government and derive their powers from specific Congressional statutory delegations, the Office of Management and Budget and its Office of Information and Regulatory Affairs (OIRA) are an extension of the President, one of the three Constitutional branches of government, deriving their powers from the Constitution and Presidential direction. Even if there were no Paperwork Reduction Act or regulatory review Executive order, OMB and OIRA could provide direction to the agencies with regard to the policies of the Chief Executive.[1] Accordingly, OMB's and OIRA's authority to provide policy guidance to the agencies on regulatory or paperwork matters is not confined by the specific directives contained in statutes or Executive orders.

I start with this point because it appears that many, including perhaps some within OMB and OIRA, seem to think that OMB's and OIRA's powers are constrained tightly by legislation and

[1] The power of Congress to control OMB and OIRA to any extent derives from the coercive power of the purse. If Congress does not provide sufficient funding to OMB and OIRA, their ability to supervise the agencies is limited. Any attempt by Congress to constrain severely or explicitly OIRA supervision of the agencies and its Presidentially-derived powers to "take care that the laws be faithfully executed" (U.S. Constitution, Art. II, sec. 3) would raise serious separation of powers issues.

The U.S. Supreme Court has recognized the power of the Chief Executive to provide policy direction to the agencies in areas where Congress has not clearly spoken. In *Chevron*, the Court stated: "[A]n agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices . . . ." 467 U.S. 837, 865-66 (1984).

Executive order, and therefore they cannot convey Presidential policy preferences to the agencies unless they have been given specific authority to do so. OMB and OIRA do indeed generally follow the directions of the President and Congress, but their authority is not necessarily limited to what is set out in written directives, whether Presidential or legislative.[2]

The Obama Administration has been, and continues to be, confronted with diverse regulatory and paperwork policy issues -- for example, with regard to finance, energy, health care, and the environment. At the same time, it has undertaken reviews of the regulatory review Executive Order, E.O. 12866,[3] and its implementation of the Paperwork Reduction Act's information collection provisions.[4] These Executive Branch reviews appear to have introduced some ambivalence into OIRA's oversight of agency policy in these two areas during the last year, thereby subtly detracting from its ability to implement Presidential policy. I will present two examples of situations illustrating such ambivalence, one involving regulatory review and the other involving paperwork clearance, in which OIRA had the opportunity provide policy guidance to an agency.[5] In one instance, earlier in the first year of the Administration, OIRA neglected the opportunity, deferring substantially, and unwisely, to the agency; in the other, later in the first year, OIRA appeared more forceful in exercising its powers.[6]

First Example: The HHS/CMS Medicare Regulations for Supplying Durable Medical Equipment

This regulation involves impacts on small businesses, jobs, and health care. Roughly eighty five percent of suppliers of durable medical equipment under Medicare are small businesses, many of which service Medicare beneficiaries in rural areas.

In 2003 amendments to Medicare legislation, Congress mandated a competitive bidding system for suppliers of durable medical equipment.[7] Final regulations were promulgated by HHS and

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[2] On the other hand, the President and OMB/OIRA, cannot counter a clear Congressional delegation to an agency. To do so would amount to an unconstitutional veto of legislation.

[3] On January 30, 2009, President Obama issued a Memorandum to the Heads of Executive Departments and Agencies directing OMB, in consultation with the agencies, to provide, within 100 days, recommendations on a new regulatory review Executive order to replace E.O. 12866. 74 Fed. Reg. 5977 (Feb. 3, 2009). OMB subsequently requested public comments by March 16, 2009. 74 Fed. Reg. 8819 (February 26, 2009). There has been no further news regarding such recommendations or a new Executive order.

[4] On October 27, 2009, OMB requested public comments on "Improving Implementation of the Paperwork Reduction Act." 74 Fed. Reg. 55269.

[5] Many PRA paperwork reviews can be the equivalent of a regulatory review because a mandatory information collection is equivalent to a regulation.

[6] The Senate did not confirm a new OIRA Administrator, Cass Sun stein, until Sept. 10, 2009.

[7] The legislation is usually referred to as the Medicare Modernization Act, or the MMA. The technical acronym for the covered equipment is DMEPOS, for durable medical equipment, prosthetics, orthotics, and services.

its Centers for Medicare Services ("CMS") in 2007.[8] However, due to numerous problems, Congress, in 2007, mandated CMS to start over on the competitive bidding.[9] As a consequence, new regulations were proposed, reviewed by the Bush Administration OIRA, and finalized on January 16, 2009, just before the Obama Administration took office.[10] The regulations were promulgated as an interim final rule, with an effective date of February 17, 2009 and a comment period ending March 17, 2009.[11]

The Regulatory Flexibility Act requires preparation of a "regulatory flexibility analysis" that analyzes regulatory options for regulations that will significantly affect a substantial number of small entities. In its review of the January 2009 final rule, OIRA approved the rule despite noting that the need for an RFA was "undetermined."[12]

The interim final rule effectively reinstated prior regulations that provided that only companies that submitted a winning bid could become suppliers even if other firms were willing to supply product at the price of the winning bid. This meant that most companies, most of which were small suppliers and many located in rural areas, would be left out in the cold. The alternative could have been to allow all accredited companies to supply equipment at the low, "winning," bid price. CMS did not examine this alternative, and stated that a regulatory flexibility analysis was unnecessary because CMS was simply implementing a Congressional directive that left it with no discretion. This is an inaccurate statement. The new legislation (MIPPA) did not address the issue.[13] In addition, the CMS interim final rule made no mention of Executive Order 13272 on "Proper Consideration of Small entities in Agency Rulemaking," which requires that agencies consider the impacts of their rules on small businesses, inform the Small Business Administration Office of Advocacy of draft

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[8] 72 Fed. Reg. 17992 (April 10, 2007).

[9] Under what is known as MIPPA, the Medicare Improvements for Patients and Providers Act.

[10] 74 Fed. Reg. 2873.

[11] HHS and CMS stated that they were dispensing with a notice and comment proposed rulemaking for good cause because the regulations were being promulgated to conform to "highly detailed and proscriptive" statutory requirements, and therefore a proposed rule would have been redundant. 74 Fed. Reg. at 2878. HHS and CMS also have authority to publish an "interim final rule" in lieu of a proposed rule pursuant to 42 U.S.C. § 1395hh(a)(3)(A).

[12] See final OIRA review conclusions at http://www.reginfo.gov/public/do/eoDetails?rrid=116685.

[13] MIPPA states only that "the Secretary shall conduct the competition for such [bidding] round in a manner so that it occurs in 2009 with respect to the same items and service and the same areas, except as provided in sub clauses (III) and (IV) ...." Sec. 154(a)(1)(d)(i)(II). However, HHS stated in its interim final rule that "[t]his regulation merely codifies the MIPPA provisions [in section 154], so there are no options for regulatory relief for small suppliers. The RFA therefore does not require that we analyze regulatory options for small businesses." 74 Fed. Reg. 2873, 2879 3d col.

rules that might have a significant impact on a substantial number of small entities, and give every appropriate consideration to comments provided by SBA Advocacy.[14]

Because the interim final rule would not become effective until after the Obama Administration took office, the Obama OIRA had a clear opportunity to re-examine it. On January 20, the White House directed all agencies to consider extending for up to 60 days the effective date of regulations that had not become effective and which raised law and policy issues in order to allow for reconsideration, and it put OMB in charge.[15] CMS extended the effective date of the DMEPOS regulation to April 17, 2009, but it never resubmitted the regulation to OMB, and OMB did not direct CMS to resubmit it.

The consequence is that a very large number of small businesses, along with their jobs, are no longer eligible suppliers, and many rural Medicare beneficiaries are losing their local rural supplier with whom they are used to working.

Our Center for Regulatory Effectiveness ("CRE") established an "interactive website" and hotline where suppliers and their customers could express their views, and it has been deluged with complaints about the loss of small rural DMEPOS suppliers.[16] CRE has also brought the issue to the attention of the Obama OIRA through the paperwork clearance process associated with the regulations, but so far there has been no action by OIRA to re-examine the issue of the need for an RFA and the alternative of allowing any supplier to supply equipment at the low bid price.

OIRA and CMS have been fully aware of these consequences but so far have chosen to ignore them, or at least not subject them to careful scrutiny.

To date, the CMS competitive bidding rule for durable medical equipment has certainly been a failure under the regulatory review process because of the failure to ensure that the Regulatory Flexibility Act and E.O. 13272 are implemented as intended and that alternatives are considered that will save small businesses, jobs, and competition.

As discussed above, OIRA has the Constitutional authority -- indeed, the responsibility -- to direct an agency to re-open a rulemaking and reconsider alternatives if it finds that a rule might not be in compliance with the law and Presidential policy. However, the OIRA mindset sometimes appears to be, as in this case, that its opportunity to review the final rule passed when the rule became

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[14] 67 Fed. Reg. 53461 (Aug. 16, 2002). Because CMS did not notify SBA Advocacy of the draft rule, as required by the Executive Order, there were no comments from SBA.

[15] 74 Fed. Reg. 4435 (Jan. 26, 2009).

[16] The CRE Interactive Public Docket on the CMS Competitive Bidding Rule can be accessed through http://www.thecre.com and the brown box in the upper right-hand corner. Public comments submitted to CRE can then be accessed through the "Discussion Forum" link in the upper right-hand corner of the interactive public docket webpage. CRE has also advised suppliers and beneficiaries to send complaints to the Medicare Competitive Acquisition Ombudsman established by MIPPA.

effective and it should refrain from any further policy action in the absence of a specific Presidential directive.

Second Example: The EPA Endocrine Disruptor Screening Program Test Requirements

This example involves OIRA review of an EPA interpretation of an environmental science statutory provision during a paperwork review. The policy issue was whether to allow businesses more flexibility in meeting the scientific testing requirements of the statute.

Congress mandated an endocrine disruptor screening program (the "EDSP") in 1996 amendments to the Federal Food, Drug, and Cosmetic Act.[17] However, the wording of the Congressional mandate was ambiguous. The statute required EPA to set up a screening program, using "appropriate validated test systems and other scientifically relevant information." Because the program would require entities to provide scientific test information to the agency, the information requirements had to be reviewed by OIRA under the provisions of the Paperwork Reduction Act ("PRA").

It was EPA's view that screening had to be conducted using its screening tests, and that "other scientifically relevant information" ("OSRI") could only be used to supplement test results rather than to substitute for use of the tests. It was OIRA's view that such a reading of the statute was too restrictive and not consistent with Congressional intent regarding the EDSP and its policy of minimizing paperwork burdens. It was recognized that many companies have already accumulated substantial scientific test data on the endocrine disruption potential of certain chemicals such that requiring new tests with the same end would serve no purpose. (In other words, in the terminology of the PRA regulations, the tests would not have "practical utility.")

Although there was considerable challenge in public comments, and even in peer review reports, to EPA's view that its screening tests had been "validated," as required by the statute, OIRA deferred to the agency on this scientific issue, but took the view that companies should be able to submit OSRI "in lieu of performing all or some of the Tier I endocrine disruptor screening tests, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible." This OIRA view was articulated in the OIRA "Terms of Clearance" incorporated into the official PRA clearance and assignment of the required OMB control number[18]; and it was also reflected in the test order instructions issued by EPA. This review action demonstrates a more careful scrutiny by OIRA of the flexibility allowed by the legal authorities with a view to reducing unnecessary paperwork and regulatory burdens and maximizing the practical utility of the EDSP program.

However, the OIRA paperwork approval might not be the end of the matter. The OIRA clearance appears to leave EPA with discretion to determine when OSRI is sufficient to be accepted in lieu of the screening assays. When companies submit OSRI, there might be instances in which

[17] 21 U.S.C. 346a(p), as added by Pub. L. 104-170, Aug. 3, 1996, the "Food Quality Protection Act of 1996", which amended sec. 408 of the Federal Food, Drug, and Cosmetic Act.

[18] The OIRA clearance document is available at http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0176#.

disputes arise over the sufficiency of the data to "satisfy the test orders." In such cases, will OIRA exercise its PRA discretion to re-open the PRA clearance and modify its terms of clearance to cover such cases? In my view, it should, if it is clear that EPA is not complying with the terms of clearance. The PRA and OMB's PRA regulations specifically provide for petitions to review any collection of information or re-opening of a paperwork clearance on its own initiative under certain circumstances, although OIRA has rarely, if ever, exercised these authorities.[19] Further, OIRA's authority to revisit an information collection approval, particularly if it was conditioned on terms of clearance, should not be viewed as circumscribed by those regulatory provisions.

Recommendations

The above examples show how OIRA can exercise the Chief Executive's authority to "take care that the laws be faithfully executed" in accordance with both Congressional mandates and Presidential policy. However, I believe they also illustrate that at times (particularly during the transition to this new Administration, and with some of its key delegations under review) OIRA has been unsure of its ability to scrutinize and on occasion substitute its views for those of an agency when it is not able to invoke specific regulatory or Executive order authority.

As I have also indicated, I believe OIRA should not view its authority as depending solely on regulations and Executive orders. As part of the Executive Office of the President, it acts as an agent of the President, and its powers are derived from the Constitution and are not limited by specific statutory delegations or regulations as are the powers of the agencies. It would be useful if this point were clarified by the President if and when he issues a new regulatory review Executive order, or by memorandum.[20]

More specifically, I would recommend the Obama Administration take the following actions:

(1) Require independent agencies to submit their regulations to OMB for review.

(2) Announce that final agency actions under the Data Quality Act are judicially reviewable.

(3) Provide a substantial increase in OIRA staff to review the regulations of independent agencies, particularly those related to the financial industry.

(4) State clearly in any modification to EO 12866 that OMB's regulatory review authorities are not dependent upon a delegation from Congress.

(5) Utilize the ongoing review of the ICR for the CMS competitive bidding DMEPOS program to compel CMS compliance with the RFA by allowing all qualified bidders to sell products at the price arrived through the competitive bidding process.

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[19] 44 U.S.C. § 3517(b) and 5 CFR § 1320.10(f) and (g).

[20] To some extent, the existing E.O. 12866 reflects this need to continually re-examine existing regulations. See sec. 5 of the order. During the Bush Administration, OIRA also, on its own initiative, began the practice of issuing "prompt letters" to agencies to encourage agencies to improve or give priority to certain regulations or regulatory issues. See http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp.