

SENIOR CITIZENS LAW PROJECT

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Submitted electronically: <http://www.regulations.gov>

Office of the Federal Register (NF)
The National Archives and Records Administration
8601 Adelphi Road,
College Park, MD 20740

Re: Incorporation by Reference
File Code NARA-12-0002
77 Fed. Reg. 11414 (Feb. 27, 2012) & 77 Fed. Reg. 16761 (Mar. 22, 2012)

The Senior Citizens Law Project of Vermont Legal Aid, Inc. (VLA) submits the following comments regarding the petition to revise regulations regarding “incorporation by reference.” We thank you for the opportunity to comment.

Introduction

VLA is a nonprofit organization founded in 1968 that provides civil legal assistance to citizens unable to afford private legal advice. The Senior Citizens Law Project represents Vermont residents aged 60 and older in a wide range of civil legal issues.

In general, regulations must be published in the Federal Register and codified in the CFR. An agency can comply with this publication requirement by incorporating by reference documents published elsewhere, but only if those documents are “reasonably available to the class of persons affected thereby” and the agency secures the approval of the Director of the Federal Register.

We believe that incorporated materials are not “reasonably available” to low-income seniors unless they are available for free. Many Vermont seniors cannot afford to pay for the privilege of reading documents incorporated into state and federal regulations. A disabled, low income senior citizen living in rural Vermont has as much right to know the law as any other American. While it costs money to create rules and standards, requiring people to pay for the privilege of reading federal regulations is an impermissible way of covering those costs.

Charging a fee for access to regulations prevents the poor from knowing the law. For example, one tenant needed to know whether her apartment complied with state fire codes. The tenant was shocked to discover that she would have to pay a large fee to find out whether her fire extinguisher met the housing code's requirements. In litigation, the court had authorized her to proceed *in forma pauperis* ("in the form of a pauper"), and her filing fees were waived by the court. There was, however, no free way for her to find the fire regulations, and no way to petition for a waiver of the purchase price.

While the fire code involved state rules, federal regulations raise the same issues. Consider an elderly woman who is confined to a wheelchair and is unable to pass through a doorway in her nursing home. She wants to figure out whether the doorway complies with federal regulations. If the relevant standards are available only for a fee, she will not be able to afford them. The state long-term care Medicaid program requires a nursing home resident to pay nearly all of his or her monthly income to the nursing home. The resident is allowed a "personal needs allowance" of only \$47.66 per month, a sum which must cover all the resident's monthly non-medical expenses.

Similarly, high costs make Medicare Part D standards unavailable to the poor. The regulations governing Medicare Part D provide that off-label use of a prescription drug is covered only if the off-label use appears in one of three privately published compendia. 42 C.F.R. § 423.100.¹ Rare medical conditions often do not appear on drug labels; as a result, roughly 90 percent of patients with rare conditions are prescribed medications off-label.² In order to seek Medicare coverage, a patient with a rare medical condition needs to know whether her off-label medication is included in the compendia. Unfortunately, access to DrugDEX, one of the compendia, starts at \$6,000. This usually means that Medicare beneficiaries must file appeals without knowing whether they meet the "compendium requirement."

1.a.i Does "reasonably available" mean that material should be available for free?

"Reasonably available" means that the material should be accessible at the same cost as the Federal Register: for free. The rationale behind incorporation by reference is that an agency can avoid the need to republish lengthy materials if the material being incorporated is already as accessible as the federal register itself. If material can only be read by paying a large fee, the material is entirely unavailable to people who cannot afford the fee.

Existing practice already recognizes this by requiring incorporated materials to be made available for free at the office of the agency publishing the regulation. Unfortunately, the way it is made available for free poses an insurmountable barrier to the poor, the disabled, and people living far from Washington DC. Section 508 of the Rehabilitation Act of 1973 requires federal agencies to make electronic and information technology accessible to those with disabilities. *See* 29 U.S.C. § 794. The current practice of making materials available for free, but only to those able-bodied enough to travel to Washington DC, is inconsistent with the Rehabilitation Act.

¹ The Southern District of New York has found that this "compendium requirement" is not a reasonable interpretation of the governing statute. *Layzer v. Leavitt*, 770 F.Supp.2d 579, 584 (S.D.N.Y.,2011).

² "Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA Approved Drugs," O'Reilly, James, and Amy Dalal, *Annals of Health Law*, 2003.

If the materials need not be free, the OFR must face the impossible task of drawing the line somewhere else. Materials that cost a million dollars to access surely are not “reasonably available.” A cost of \$100 may be no barrier for a large corporation, but would make the materials entirely unavailable to an indigent senior. If the OFR does not require materials to be provided free, it will need to find a different dollar threshold ensuring that materials are available not only to the prosperous, but also to the poor.

1.a.ii Does “reasonably available” mean that material should be available to anyone online?

While it is not necessary to make the material available online, that is probably the cheapest way of making it reasonably available. As an alternative, it would be equally acceptable to mail free paper copies of the material to anyone who requests it. Providing the material online is probably cheaper. Material is not “reasonably available” if it can be accessed only by paying a large fee or trekking to a distant repository.

1.b. Would making material available online create a digital divide by excluding people without Internet access?

No. Adding online access to materials incorporated into federal regulations increases access for everyone, including people without internet access at home. The local library or senior center in a rural Vermont town will have a computer terminal with internet access, but is unlikely to have copies of all the materials incorporated by regulations in the federal register. Even a homebound senior citizen without internet access can ask a friend, relative, or advocate to print online materials. Online access does not reach everyone, but it significantly narrows the divide between people those who can currently afford access to federal regulations and those who cannot afford access.

A digital divide may be created if online access to materials is “read-only,” depriving the public of the ability to print or copy the governing law. When the online access prohibits the viewer from printing out the rules, people without internet access at home are put at a disadvantage. Read-only access means that a senior citizen who reads the relevant regulations at the library cannot print them out to review at home or ask someone else to print out the regulations for her. For this reason, online materials should not be considered “reasonably available” unless viewers have permission to print the materials.

2. Does “class of persons affected” need to be defined? If so, how should it be defined?

No, the “class of persons affected” varies by situation and should not be given a single definition. Rules governing accessibility of public buildings affect not only architects and building owners, but also every member of the public who may enter the building. Rules governing the safety of toys affect not only toy manufacturers, but also toy vendors, consumers who want to know if their toys are safe, and concerned citizens who want to know whether their relatives and neighbors are protected from unsafe toys. Environmental regulations affect not just the power plant, but also the people living downwind from the smokestack.

It is also necessary for proposed regulations be accessible to the public as a whole for comment. That is part of why Congress created the Federal Register. Incorporated materials are “reasonably available” to regulated *and other interested* parties.

3. Should agencies bear the cost of making the material available for free online?

The federal government bears the cost of making all federal regulations available for free online. If an agency is incorporating materials that are already available for free online, it can avoid the cost of publication in the Federal Register. If an agency wants to incorporate materials that are not already reasonably available, it must publish those materials in the Federal Register or arrange for the materials to be made available for free.

If an agency decides that paying to make outside materials available online is more cost effective than creating its own materials, the agency may decide to do so. If it would be expensive to provide access to certain materials, the agency may decide not to incorporate those materials, or it may bargain for a licensing agreement with the standards development organization.

4. How would this impact agencies’ budget and infrastructure, for example?

There is no evidence that making incorporated standards available for free on the Internet would unduly impact agencies’ budgets and infrastructure. Agencies will become less inclined to adopt regulations incorporating materials that are not already available to the public. Standards organizations may well decide to make their standards available for free in order to have their standards incorporated into federal regulations. If an agency does not want to bear the cost of making incorporated materials available for free online, it can instead publish the materials in the federal register.

5. How would OFR review of proposed rules for IBR impact agency rulemaking and policy, given the additional time and possibility of denial of an IBR approval request at the final rule stage of the rulemaking?

The choice is not between IBR review and no having IBR review, it is between the existing review and improved review. OFR is already required to review proposed rules for IBR. 5 USC § 552(a)(1)(E). (“[M]atter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.”).

If OFR responds to this petition by promulgating clear rules for the conditions under which standards may be incorporated into proposed regulations, agencies will see a reduced risk that IBR approval will be denied. It is quite simple for an agency to figure out whether its proposed regulations are incorporating materials that are available for free online.

A clear standard will save agencies time and expense by protecting the agencies from legal challenges after the regulations are promulgated. Without adequate IBR review, agencies that fail to ensure that IBR materials are reasonably available are likely to face noncompliance and costly litigation. *See, e.g.* Appalachian Power Co. v. Env’tl. Prot. Agency, 566 F.2d 451, 455 (4th Cir.

1977) (holding that a document EPA intended to incorporate by reference into a regulation was “not a validly issued part of the regulations, because it ha[d] not been published in the Federal Register, nor ha[d] the procedural requisites for incorporation by reference been complied with”).

6. Should OFR have the authority to deny IBR approval requests if the material is not available online for free?

Yes, OFR has authority to deny approval of incorporation by reference if the material is not “reasonably available.” 5 USC § 552(a)(1)(E). As discussed above, we believe that material is not “reasonably available” unless it is available for free, just like the federal register itself.

7. The Administrative Conference of the United States recently issued a Recommendation on IBR. 77 FR 2257 (January 17, 2012). In light of this recommendation, should we update our guidance on this topic instead of amending our regulations?

Both the regulations and guidance should be updated. There is no reason to update one and not the other.

8. Given that the petition raises policy rather than procedural issues, would the Office of Management and Budget be better placed to determine reasonable availability?

No, deferring to the OMB would be inconsistent with the governing statute. Congress has designated the Director of the Federal Register as the person responsible for deciding whether something is exempt from the usual requirement of publication in the Federal Register and can instead be incorporated by reference. 5 USC § 552(a)(1)(E).

9. How would an extended IBR review period at both the proposed rule and final rule stages impact agencies?

In most cases, improved IBR review should have little impact on agencies. So long as “reasonably available” is clearly defined, extended IBR review will not be necessary. An agency can determine whether materials are reasonably available before it proposes incorporation. Revising the regulation adds predictability for agencies and allows them to figure out in advance whether materials can be incorporated by reference.

Improved IBR review would assist agencies by preventing them from promulgating rules in a fashion that renders them illegally inaccessible to the public. This would meet the agencies’ interest in complying with governing law by making their rules reasonably available. IBR review would also prevent agencies from attempting IBR and then discovering through costly litigation that incorporated materials are not binding on regulated parties. Agencies will also benefit from IBR review because making incorporated materials available will increase compliance by regulated individuals, reducing the need for costly enforcement actions.

Conclusion

Thank you for the opportunity to submit comments on this important topic. If you have any questions about these comments, please contact Jacob Speidel at (802) 885-5181 or by email at jspeidel@vtlegalaid.org.

Sincerely,

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