

How to comment on government regulations

By Eileen Shannon Carlson, RN, JD

THE AMERICAN NURSES ASSOCIATION (ANA) wants to help you channel your valuable nursing knowledge and experience into regulatory comments that can improve healthcare policy, patient care, and the practice and working environment of nurses. Nursing is the predominant and most trusted healthcare profession. Nurses have more direct patient care and patient contact than any other healthcare professionals.

Nurses care for all types of patients in all methods of care and in all settings. Our expertise and knowledge are highly valued by policy makers. All nurses have a unique viewpoint, evolved from our individual experiences. And you can make a difference by submitting your comments to federal departments and



agencies. It's the easiest way to get directly and personally involved in developing public healthcare policy. This article provides guidelines to help you navigate your way through federal regulatory issues and develop your own comments.

Why should you care about federal regulatory actions?

Federal departments and agencies employ millions of workers to run the government and develop policy. (See *Key healthcare players*.) With leaders chosen by the White House, they work within the framework of laws passed by Congress and executive orders issued by the President. Federal regulations, which these employees implement and enforce, carry the force of law and are embodied in the U.S. Code of Federal Regulations. Notices of proposed rulemaking (NPRMs) are documents that propose new or amended regulations; final rules contain the final version.

Why are public comments important?

Federal laws ensure the regulatory process is fair, open, and consistent. The Administrative Procedure Act guar-

Your nursing experience and perspective can influence healthcare policy.

antees an opportunity for public comment on proposed rules and major actions. Agencies such as the Food and Drug Administration also seek public input on documents, as well as through workshops and meetings. Most important, regulatory bodies must take public input into account when finalizing their rules or decisions; otherwise, the courts could reverse these as being “arbitrary and capricious.” So regulatory officials review *every* public comment letter, and commonly respond to particular comments in final rules.

Why are nurses' views important?

Many health policy staff and decision makers have backgrounds in political science or business, with little to no clinical experience. Although charged with serving the American public, they have limited direct contact with the people they serve. With nurses' dual roles in direct care and patient advocacy, we can address both these crucial areas, so our input is encouraged and often highly valued. Also, physicians, hospitals, and insurers consistently maintain a strong and vocal presence on many regulatory issues.

How do you get started?

If you know of a proposed rule open for comment, you can find it on www.regulations.gov. This is also where to submit comments online and read comments already posted. Official NPRMs or other actions are published in the *Federal Register*, which is available in libraries and online at www.fdsys.gov; this website provides the most condensed and readable version.

Many NPRMs follow a typical format and order: directions for comments, table of contents, background section, summary of the proposed initiative, discussion of regulatory impact, tables and other technical information, and the text of the proposed regulation or amendments. Skip to the end to see the actual changes in regulations. Every notice also identifies staff available to respond to questions; don't be afraid to contact them directly. Additionally, federal advisory panels announce



Key healthcare players

Each federal agency and department has a certain degree of autonomy and independence. The Internal Revenue Service, Federal Bureau of Investigation, and Federal Reserve have sweeping powers. A few agencies and departments even have their own court systems.

Here are the key players in health policy:

- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention (CDC)
- Agency for Healthcare Research and Quality (AHRQ)
- Environmental Protection Agency (EPA)
- Health Resources and Services Administration (HRSA)
- Occupational Safety and Health Administration (OSHA)
- Medicare Payment Advisory Commission (MedPAC).

their meetings and requests for nominees through the *Federal Register*, including many devoted to particular healthcare issues; some of these panels include nurses as members, or might include them in the future.

If you have a general area of interest but don't know where to start, visit websites of agencies and healthcare organizations. Know that public comments can be submitted at any time. ANA posts summaries and links to its regulatory comments on www.nursingworld.org. The Centers for Medicare & Medicaid Services (CMS) website, www.cms.gov, offers a wealth of excellent resources. CMS policies for Medicare and Medicaid serve as guidelines for many areas of health care. Proposed rules to update the various Medicare payment systems (for instance, in/outpatient and physician fee schedule) have comment periods. The Medicare Payment Advisory Commission accepts comments online regarding topics of pending meetings at www.MedPAC.gov.

How do you write regulatory comments?

There's no one correct way to write comments. Your comments should reflect your own thoughts and personality. But here are a few guidelines designed to help you advocate effectively on your issue. (Also, feel free to use ANA comments as a model.)

- **Address the right agency and official.** Address *formal* comments to the official who signed the NPRM or the highest ranking official of the agency, to ensure disbursement to all appropriate staff and officials. You can also send *informal* comments directly to a staff member, but these may not go to decision makers or be considered official comments. With no NPRM, verify you're addressing the correct agency; otherwise, your comments may be lost.
- **Introduce yourself.** Describe your professional background and relevant work or personal experience in a few sentences. Put your professional credentials after your name and include contact infor-

mation (such as your e-mail address) in case recipients have questions. Comments from individual healthcare providers are greatly appreciated, but comments also can be written on behalf of a group, an employer, or a department.

- **Be clear and succinct.** Clearly state the issue and your position. This seems obvious, but it's important to keep in mind. Sometimes the issue gets lost in the message or the position seems unclear. Express your views as briefly as you can to get your point across; a page or two is fine.
- **Offer solutions.** Try to mention something you like about what the agency is doing, even if you are incensed about the issue at hand. Offer suggestions for alternative solutions.
- **Include real-world examples.** Personal views and stories are highly valued, especially those showing how a proposed policy may affect patient care and nursing practice. Also, know that *briefly* mentioning something that tugs at the heart strings or touches the reader on an emotional level can be highly effective.
- **Include evidence.** If appropriate, cite supporting studies and data. This demonstrates your professionalism and seriousness about the issue, which you obviously believe warranted the time to research.
- **Educate.** Assume reviewers know nothing about clinical care, nursing practice, and the nursing profession. This is an opportunity to educate them.
- **Don't include anything confidential.** Your comments will be considered a public document. Don't even think of identifying patients or otherwise divulging their identity through detailed descriptions, disparaging coworkers or employers, or including other confidential information. Identifying patients is a violation of the Health Insurance Portability and Accountability Act that can lead to large fines.
- **Endorse others' comments.** If someone else has expressed your position perfectly, it's fine to simply write that you support and endorse their comments. You don't need to reproduce them.
- **Be neat.** Avoid typos and grammatical errors. Use professional language and consistent style. For longer comments, consider using issue headings to help refer your comments to the appropriate staff.

What if you have more questions or comments?

I work on regulatory issues and lead ANA's interdepartmental regulatory team. I'm happy to help with questions, and I would appreciate your feedback. We'd love to know when ANA members, state and constituent member associations, and organizational affiliates submit comments. You can contact me at eileen.carlson@ana.org. ★

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