

February 22, 2021



Gail Bormel, RPh, JD
Acting Director
Office of Compounding Quality and Compliance
U. S. Food & Drug Administration

Dear Dr. Bormel:

In late winter 2020, the Alliance for Pharmacy Compounding (formerly IACP) established as one of its five strategic ends – the broad outcomes we aim to effect as an organization – the work of encouraging and elevating the highest standards of ethical behavior among pharmacy compounders. *I am writing to brief you and your CDER team on the work we're doing to realize that outcome.*

As you may know, APC is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as educators, students, researchers, and suppliers. Our members play a critical, life-sustaining role in patients' lives, creating essential medications unavailable elsewhere for a range of health conditions.

In the wake of serial scandals by bad actors in the compounding space, APC has begun to play a greater role in enunciating to – and beyond – our members a set of broad standards for ethical practice and behavior in pharmacy compounding. We believe this work is essential and that continually reminding compounders of their ethical obligations will not only help protect patients but also elevate the pharmacy compounding profession.

Following are four substantive actions we have taken or are working on.

Pharmacy Compounding Professional's Code of Ethics. In late 2020, the APC Board of Directors approved a new Compounder Code of Ethics developed by a special APC Ethics Working Group chaired by Dr. Loyd Allen of Edmund, Oklahoma. The new Code of Ethics includes 10 commitments focused on clinical practice, professional development, business practices, and serving as ambassadors for the profession. As an aspirational document, it is meant to be a North Star for compounders, and we have begun to promote it and inculcate it via our communication and education offerings, as you will read below.

The new Code is available at www.a4pc.org/ethics, including a printable, frameable version many members have already chosen to post in their pharmacy or facility.

APC members subscribe to the Code of Ethics. To emphasize the importance of ethical practice and the precepts of the Code of Ethics, APC members will be required to indicate a commitment to the Code of Ethics when they join our organization and upon annual renewal of membership. We believe that reminder – the act of the member indicating at least once a year

in writing that they subscribe to the standards of the Code – can be effective in part in encouraging ethical behavior. We have implemented the requirement that new members commit to the Code, and aim to have it implemented for renewing members by July 1, 2021.

Sustained focus on the Code and its precepts in APC communications and training.

1. **Pharmacy Compounding Leader.** In January, we debuted the new Code of Ethics to our members via a new publication that not only shared the Code but also spotlighted pharmacy compounding professionals who live its precepts in their work. You may view the newsletter at www.a4pc.org/code.
2. **Best Practices in Pharmacy Compounding Conference.** Earlier this month, we hosted our first-ever conference focused on ethical practice and the new Code of Ethics. More than 130 attended.
3. **Free training video on the new Code of Ethics.** We have made available free of charge the recording of a session presented at our Best Practice Conference by ACHC's Jon Pritchett on the new Code and are urging pharmacy compounders to use it in training their teams. That video is available at www.a4pc.org/code.
4. **The Ethical Thing to Do.** This coming week we'll start an occasional column called The Ethical Thing to Do in our weekly member e-newsletter. The column will posit an ethical quandary or decision point compounders may face, and an attorney will provide an answer and point to the section of the Code of Ethics that addresses that issue.

Proposed certificate program: Ethical, Legal & Regulatory Framework of Pharmacy Compounding. We are developing a 15-hour foundational certificate program on the ethical, legal and regulatory framework of pharmacy compounding, using our new Code of Ethics as the broad outline for the course. We hope to launch it by the end of 2021.

These examples demonstrate the sort of sustained focus we aim to maintain on the precepts of the Code and our members' obligations under those precepts. We believe it's an essential step in elevating the compounding profession and assuring the highest level of patient care.

Nothing in this letter requires response or action on the part of FDA. I share it for your information. Please contact me if I may be helpful to you or your team.

Sincerely,



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