

AARP - meeting - minutes  
 - David's picture

Drugs Over Internet File

**DRAFT: REVIEW OF PROPOSED LEGISLATION ON PRESCRIPTION DRUGS AND  
 THE INTERNET  
 March 14, 2000**

The draft legislation essentially conforms with the Presidential announcement made on December 28<sup>th</sup>. However, based on additional feedback from the agencies and staff internally, the following changes have been proposed.

The goal is to have legislation up to the Hill before FDA's hearing on 3/21/00.

**CERTIFICATION OF COMPLIANCE FOR ON-LINE PHARMACIES**

**AS DRAFTED:** On-line pharmacies are required to demonstrate to HHS prior to their launch that they are in compliance with state and Federal law. After going on-line, the pharmacy must display a seal of Federal compliance on their website.

**PROPOSED CHANGES:** The requirement that on-line pharmacies would demonstrate compliance to FDA prior to launch would be deleted. The requirement to display the seal of compliance would be deleted. The seal of compliance would be replaced with the standardized website disclosure information (see below).

A requirement for on-line pharmacies to register with the state and with FDA prior to launch would be added. On-line pharmacies that are currently operational would be given up to 6 months to register.

**RATIONALE:**

This change was proposed to satisfy the concerns of both the E-Commerce working group and OIRA, who believe that: (1) this violates the WH policy that on-line and off-line entities will be subject to the same requirements, and (2) FDA will not be able to review the new applicants in a timely fashion. I do not think they will be flexible on this point. However, although this change eliminates certification of compliance to FDA prior to launch, it still achieves the majority of the original provision's goals.

The requirement to post standardized website disclosure information both provides overarching grounds for Federal enforcement and prosecution of sites that are out of compliance and an easily recognizable signal to consumers that this is a legitimate site. In addition, the requirement to register with FDA prior to allows the agency to begin to track the proliferation of these websites in an organized fashion, making enforcement easier.

The obvious problem is that we are backing away from the original POTUS announcement, which was very clear on this point. FDA will not support this change. It is important to note that the pharmacies still support the use of a Federal seal, and are even willing to pay a user fee to absorb some of the cost of monitoring these sites.

**WEBSITE DISCLOSURE INFORMATION**

**AS DRAFTED:** The on-line pharmacy must post on its homepage: the name of the on-line pharmacy identified on its license to practice; the street address of the pharmacy's principal place of business; the name, professional degree, and licensure of the pharmacist in charge, a telephone number at which a licensed pharmacist may be contacted; a list of the states in which the pharmacy is licensed to dispense drugs and the license numbers; and the declaration that the pharmacy will dispense prescription drugs only in compliance with state and Federal law.

**PROPOSED CHANGES:** The requirement that this information be posted in a standard place on the webpage, with standard requirements for font-size and layout that are at the Secretary's discretion, will be added.

**RATIONALE:** This change was proposed to ensure that posting the disclosure information will serve to immediately identify the site as legitimate. No one objects to this change.

**ADDITIONAL OPTION:** OVP would like to add a requirement that the disclosure information include a declaration that the site is operating in full compliance with state and Federal law.

**RATIONALE:** I believe that to allow entities to self-certify their compliance with Federal law is misleading. We are checking to see if FDA permits this in any other situation. I believe this provision should be deleted. OMB is neutral on this provision. OVP has made the point that if they make the statement and it is false, they can be prosecuted by FTC for false statements as well as FDA and DOJ for the actual violation.

**ADMINISTRATIVE SUBPOENA AUTHORITY**

**AS DRAFTED:** FDA would receive administrative subpoena authority to investigate on-line pharmacies.

**PROPOSED CHANGES:** There is no staff-level consensus on this provision. Options include:

1. Eliminating the provision.
2. Providing the authority to DOJ rather than FDA.
3. Providing the authority to DOJ/FDA for both on-line and off-line pharmacies.
4. Retaining the provision as currently drafted.

**RATIONALE:**

OVP objects to this provision because they feel it violates the WH policy that on-line and off-line entities will be subject to the same requirements. OMB disagrees, as do I. Without this provision, FDA must go through a grand jury to receive a subpoena - a long and burdensome process. This provision is essential to ensuring that FDA can move quickly enough to gather the necessary material to build a case against bad actors.

Although it does go outside the boundaries of the standing WH policy by providing this new authority to FDA for the investigation of *only on-line pharmacies*, this is condoned by the recently released DOJ report on unlawful conduct on the Internet, which states that "...it may be necessary to alter or augment law enforcement's tools and authorities to meet the new investigatory challenges that unlawful conduct presents."

DOJ's only concern on this issue seems to be that we would provide the new authority to FDA, and not to them.

I think that actually getting the authority is more important than which agency gets it. I also think that providing this authority to the Federal government for both on and off-line pharmacies would raise enough resistance from the private sector to kill the entire provision - that's a huge expansion of FDA authority. I think we should support option 4, and as a fall-back, option 2.

**PENALTIES FOR NON-COMPLIANCE**

**AS DRAFTED:** In addition to the proposed civil money penalties, if at any time, the Secretary finds that a website fails to meet any of the requirements in the statute, she can deem it to be unlawful for the pharmacy to engage in or offer to engage in the delivery or sale of a prescription medication.

**PROPOSED CHANGES:** This language provides HHS with a wide range of discretion when determining when to close down websites. The language should clarify that closing down a site is: (1) a last resort, and (2) can only be done after a site operator has had the chance to appeal the decision.

**RATIONALE:**

I think that this is probably just a drafting error and that FDA will have no problem fixing it.

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*User fees for transmittal letter*

## **REQUIREMENT FOR A VALID PRESCRIPTION**

**AS DRAFTED:** Requires that prescriptions be based on a physician patient relationship that is not based primarily on an on-line questionnaire or other document.

**PROPOSED CHANGES:** Together with the requirement that pharmaceuticals be dispensed in accordance with state law, this requirement is a little redundant and also seems to intrude on the state regulation of the practice of medicine. It should be deleted.

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**PROPOSED CHANGES:** This language provides HHS with a wide range of discretion when determining when to close down websites. The language should clarify that closing down a site is: (1) a last resort, and (2) only after following applicable administrative procedures, including appropriate due process requirements.