How Changes To 'Dear Doctor Letters' Will Impact Industry

Law360, New York (March 31, 2014, 5:59 PM ET) -- The U.S. Food and Drug Administration’s guidance on "Dear Health Care Provider" ("DHCP") letters, finalized earlier this year, provides further clarity on the agency’s expectations for the content, format and use of the communications that manufacturers issue to convey important, newly-discovered safety and other information on drugs and biologics.

Despite the availability of this additional guidance on DHCP letters (a.k.a., “Dear Doctor letters”), however, ambiguities remain as drugmakers and a broad array of health care providers prepare to operationalize the FDA’s recommendations. Manufacturers appear to be left with notable discretion in determining the appropriate target audience for a DHCP letter in light of the broad parameters articulated by the FDA in the final guidance. Manufacturers will likely continue to grapple with the challenges of balancing the need to issue DHCP letters in a timely fashion following the discovery of new or updated information regarding a drug with the potential benefits of preliminary consultation with the FDA in developing the letter.

Furthermore, health care recipients and potential recipients of DHCP letters should consider developing or revisiting any existing protocols for receiving and addressing the information communicated in the letters, particularly as a greater number of health care professionals may become recipients of them from drugmakers as a result of the final guidance. While FDA guidance documents are not binding, they represent the agency’s current interpretations and thinking on regulatory requirements and on its enforcement approach.

Background

The guidance, published on Jan. 22, 2014, finalizes a draft guidance document the FDA issued in November 2010 that provides recommendations regarding when it is appropriate for a drug manufacturer to issue a DHCP letter, information on the various types of DHCP letters and recommendations on the content and format of such letters. The guidance also encourages manufacturers to consult with the “appropriate review division” of the FDA to determine the appropriateness of issuing a DHCP letter, the presentation of information in the letter, the target audience and the time frame for distribution, which should provide that “the intended audience receives the information promptly, as appropriate to the issue being communicated.”

Of particular note, the final guidance retains a recommendation — which some stakeholders objected to — that DHCP letters be distributed to health care providers likely to prescribe the drug at issue, to any health care provider likely to “dispense” “or administer” the drug “as well as others who need to know the information,” even if they do not prescribe, dispense or administer the drug.
In a notice addressing comments it had received on the draft guidance, the FDA explained that its recommendations are intended to clarify the regulatory requirement that manufacturers communicate “important information ... to physicians and others responsible for patient care,” and that they reflect the current realities “of the health care system today, which has a variety of practitioners involved in patient care.”

Separately, the FDA removed a recommendation in the draft guidance that called for manufacturers to conduct an assessment of the extent to which a DHCP letter has the effect of altering the behavior of the target audience as intended. Additionally, the agency revised its original recommendation that manufacturers evaluate the extent to which the target audience received and is aware of the information in a DHCP letter, providing, instead, in the final guidance that manufacturers should conduct such evaluations “for their own use.”

Implications and Operational Considerations

Notwithstanding certain concessions, that the FDA granted in response to comments, the final guidance may nonetheless raise significant challenges as drugmakers consider how to implement some of the agency’s recommendations. In that regard, the broad scope of health care providers and others, including caregivers, whom the FDA recommends be included in the target audience for a DHCP letter, may warrant adoption of a standard operating procedure that identifies additional criteria or guidelines to assist in determining the target audience.

Such criteria or guidelines might advise, for example, that the manufacturer’s responsible personnel take into consideration the type of drug at issue, how it is administered and the nature of the information the DHCP letter will use to identify the types of health care providers or other parties “who need to know the information” in a DHCP letter. Information regarding a newly-discovered adverse reaction, for instance, may warrant a target audience that is broader than appropriate for information relating to a change in the dose or dosage regimen.

Smaller manufacturers that — because of their more limited resources — prefer to avoid being over-inclusive as to who should receive a DHCP letter, may find it particularly worthwhile to articulate such criteria and guidelines in a standing policy to facilitate a case-by-case determination. Conversely, where there is a particular sense of urgency, whether due to the nature of the information to be conveyed or an otherwise compacted time frame, a drugmaker may decide to err on the side of over-inclusion so as to mitigate the likelihood of omitting from the DHCP letter’s target audience a party who would be encompassed by the criteria set forth in the final guidance. Ultimately, because the FDA does not provide detailed guidance regarding who might be considered “likely to prescribe, dispense or administer” a product or who might “need to know the information” in a DHCP letter, manufacturers should weigh the advantages and disadvantages of adopting a case-by-case approach as opposed to a blanket approach with regard to identifying target audiences, keeping in mind the manufacturer’s resources and the nature of its products.

Likewise, manufacturers that decide to proceed with conducting assessments “for their own use” of whether a target audience received and is aware of information in a DHCP letter should consider adopting standard operating procedures for conducting the assessments. Such procedures may also address how, if at all, manufacturers should take into consideration the information obtained from the assessments in developing and determining the target audience for future DHCP letters.

Another source of ambiguity lies in the interplay among the FDA’s recommendation that manufacturers
consult with the agency in developing DHCP letters, manufacturers’ obligations to issue communications under Risk Evaluation and Mitigation Strategies ("REMS"), and the need to ensure timely issuance of DHCP letters to mitigate potential liability under other applicable law, including state tort law.

It should be noted that the FDA regulatory provision (21 C.F.R. § 200.5) relevant to DHCP letters focuses largely on the format and manner of distributing the communications and otherwise simply provides that manufacturers “occasionally are required to mail important information” to those “responsible for patient care.” Likewise, the final guidance notes that its concepts “may be used, in appropriate circumstances, to help develop correspondence to meet certain communication plan requirements for [REMS],” but otherwise provides little clarity as to how manufacturers should coordinate and, as needed, reconcile their various obligations under the FDA’s regulations, the final guidance, REMS and other applicable federal and state law.

For example, while consultation with the FDA can no doubt be beneficial, and in some cases required (e.g., under a REMS), there have been cases that suggest obtaining agency clearance of a DHCP letter may not shield a manufacturer from liability in duty-to-warn or other litigation for alleged failure to issue the letter and/or other safety information in a more timely manner. Thus, while obtaining the FDA’s input in developing a DHCP letter may provide more certainty from a federal compliance perspective and a stronger basis on which to assert a preemption defense in state tort cases, reaching a consensus with the FDA may also raise other liability concerns due to its potential to be a time-consuming process.

Therefore, while the final guidance encourages consultation with the FDA before issuing a DHCP letter, manufacturers that choose to engage in such consultations should be mindful of the time that lapses from when they first became aware of the underlying new or updated information and the time for the FDA’s review and clearance of the letter and ensure clear communication and coordination with the FDA regarding the agency’s and manufacturer’s expectations for the time required to develop, review and approve the letter. This is a particularly important consideration in situations where the DHCP letter pertains to new or updated safety information.

Finally, health care providers and others who are in a position to “need to know the information” in a DHCP letter should be prepared to receive such communications and consider having policies and procedures in place to record and, as necessary, implement the information conveyed in the letter. As the receipt of a DHCP letter may have implications from a duty-of-care perspective, health care providers and other potential recipients should assess what, if any, obligations they have to further communicate the information, such as to patients or other health care professionals who may need to know the underlying information but who may not have received a letter from the drug manufacturer or drug distributor.

In sum, the final guidance provides a general framework for drug manufacturers regarding the FDA’s views on the appropriate content, format, recipients, timing and use of DHCP letters. While this additional guidance is welcome — particularly in light of the limited regulations that have been promulgated regarding DHCP letters — manufacturers will likely continue to grapple with the more granular, operational aspects of developing these communications. Moreover, in view of the expanded scope of recipients suggested by the FDA for the letters, and even relating to the assessment of the “impact” of such communications, manufacturers and health care provider recipients of DHCP letters should also consider the effect implementation of the guidance may have on federal and state health and tort law enforcement. A methodical and robust procedure for developing — and for health care providers, receiving and addressing — DHCP letters that takes into consideration factors and issues
beyond the four corners of the final guidance may thus be a useful tool in managing these challenges.

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