January 5, 2011

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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Docket Number 2010-D-0319 Draft Guidance for Industry and Food and drug Administration Staff
on Dear Health Care Provider Letters: Improving Communication of Important Safety Information**

Dear Sir /Madam:

iHealth Alliance is pleased to submit its comments on the **Draft Guidance for Industry and Food and
drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of
Important Safety Information** as per the notice published in the Federal Register on November 12,
2010 (Vol. 75, No. 218). Please find three comments and recommendations regarding this Draft
Guidance, respectfully submitted by The iHealth Alliance.

1. The choice of using one of the three headings; IMPORTANT DRUG WARNING, IMPORTANT
   PRESCRIBING INFORMATION, or IMPORTANT CORRECTION OF DRUG INFORMATION may not
   convey the appropriate safety risk message when a DHCP letter is part of a REMS program. We
   ask that the FDA consider the use of an additional letter heading such as IMPORTANT DRUG
   SAFETY INFORMATION. For a DHCP letter in a REMS Communication Plan this would more
   accurately communicates the letter's intent. The use of this header will also better define other
   communication materials that may be included within the REMS, such as HCP safety guidelines or
   educational safety brochures thus providing greater clarity about the purpose of the
   communication.

2. The draft guidance calls for an evaluation of the DHCP letter's penetration into the target
   audience and related provider awareness of the new information. Given the difficulties
   manufactures are encountering in engaging busy doctors with REMS assessments, the iHealth
   Alliance is asking the FDA to consider specifically calling out CME as an option in these
   assessments as a means to optimize response rates and accuracy of the assessments.

3. The draft guidance might also suggest to manufacturers to include ***online*** adverse event (AE)
   reporting as opposed to the current guidance which specifically references telephone-based
   reporting of AEs. The rapid uptake of electronic health records provides a convenient platform
   for AE online reporting as several recent studies have demonstrated.

FDH-2010-D-0319

We wish to thank FDA for the opportunity to comment on the Draft Guidance for Industry and Food and drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information. We do hope you find these recommendations have merit and will be happy to provide additional information.

Thank you and best regards,

Nancy Dickey, MD
Chairman, iHealth Alliance

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