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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
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### **Template for Submissions Regarding Implementation Date of California ePedigree Laws (Bus. & Prof. Code, § 4163.5)**

Business and Professions Code sections 4034 and 4163 provide that absent further action by the Board of Pharmacy, California electronic pedigree requirements will be effective as of January 1, 2009. Business and Professions Code section 4163.5 vests the Board with authority to extend the date for compliance with these requirements to a new date of January 1, 2011, if the Board “determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.” In other words, absent a finding by a vote of the Board that two additional years are required, the implementation/compliance date will not change.

The Board has stated that it will place on the agenda for its March 25, 2008 meeting in San Diego a discussion item regarding readiness for the January 1, 2009 implementation/compliance date. The Board may or may not vote on this issue during the meeting. In anticipation of this discussion, the Board invites any persons or entities wishing to comment on the feasibility of the January 1, 2009 compliance date to do so, in writing, in advance of the meeting. The Board wishes to receive as much information as possible from as many parties as possible, including all segments of affected industries, technology experts and vendors, academics, other regulators, members of the public, and any others with knowledge of readiness or technology development. The Board invites comment from those supporting a January 1, 2009 compliance date as well as those who assert that additional time is needed. The Board is particularly hoping to hear from those members of the industry who are on track to be ready for January 1, 2009 compliance.

Several entities that have indicated an intention to request that the Board delay the date for compliance have asked for guidance on criteria the Board may employ in making this determination. These criteria have already been articulated several times at quarterly meetings of the Enforcement Committee and the E-Pedigree Workgroup. By identifying its criteria for decision, the Board is by no means soliciting such request(s). To the contrary, although the Board will, as contemplated by section 4163.5, entertain appropriately-stated requests for delay, the Board has repeatedly made clear in prior meetings that it believes the industry ought to be able to comply with the requirements of the pedigree statutes by January 1, 2009. This is particularly the case since the electronic pedigree requirements were first legislated into California law in substantially similar form in 2004, giving a total lead time for the industry of four or more years.

With regard to the appropriate criteria, first and foremost, as with all of its functions, the Board is guided in exercise of this discretion by its overriding mandate to make protection of the California public its highest priority. (Bus. & Prof. Code, § 4001.1.) Any decision of the Board must be consistent with this priority.

Second, as provided by section 4163.5, to permit any extension, the Board must “determine” that participants in the industry “require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.” That is, the Board must be able to conclude, based on its review of all evidence before the Board: (i) that the industry is unable to implement electronic technologies in time to meet the January 1, 2009 compliance date, and specifically that its members require additional time; and (ii) that there is a material difference in terms of this readiness between January 1, 2009 and January 1, 2011. This will of course be an aggregate rather than an individual determination, pertaining to the industry as a whole rather than to the readiness of any individual industry participant.

Accordingly, any request for delay should satisfy the following:

1. It should be in writing, and should be submitted at least two weeks in advance of a full meeting of the Board. The Board will not consider any request not submitted in writing, and not received at least two weeks before a full Board meeting, e.g., by no later than March 11, 2008 (and preferably March 3, 2008) to be timely for the March 25, 2008 meeting.
2. It should be signed by/submitted in the name of the requesting person(s) or entit(ies), and if appropriate be submitted on the letterhead of the requesting person, entity or association. The Board will not consider requests for delay from anonymous or unidentified persons or entities.
3. It should be supported by specific, articulated evidence demonstrating: (i) that one or more industry members is unable to meet the January 1, 2009 compliance date, but is able to meet the January 1, 2011 compliance date, i.e., that this additional two years is required to implement necessary electronic technologies; and (ii) that this delay would enhance, and not detract from, the safety and/or protection of the California public. Any such presentation should include the following types or categories of evidence:
  - a. A specific demonstration of all efforts expended thus far by the requesting party or parties, including timelines or specifications showing date(s) on which such efforts began and progress thus far, methods employed, costs and employee hours expended, and similar data, as well as a detailed demonstration of specific barriers or obstacles to compliance by January 1, 2009, including timeline(s) and specification of efforts between date of submission and January 1, 2009, any partial compliance to be achieved, etc.;
  - b. As an extension of or part of the same timeline(s), a specific demonstration of steps/efforts necessary between January 1, 2009 and January 1, 2011 that make it possible to comply by 2011 where it would not be possible to do so by 2009, i.e., evidence that this additional time is required for implementation, including costs to be expended, specific milestones to be accomplished by which dates, etc.;
  - c. In order to show that any delay in implementation would be consistent with a first priority of the Board to protect the California public, a specific articulation or demonstration of how public protection would be served by delay, including any evidence that January 1, 2009 compliance would be detrimental to this interest or that a January 1, 2011 compliance date would better serve this interest, any anticipated developments between 2009 and 2011 that would better serve the Board's first priority to protect the public, and any additional interim measures which a requesting party is committed to taking between 2009 and 2011 to further drug distribution security pending compliance on January 1, 2011.

The Board reiterates that it hopes to receive written submissions from those who support, can attest to the feasibility of, and/or will themselves be ready for, a January 1, 2009 date, as well as those who may assert that additional time is required. To the extent feasible, the Board encourages such written submissions of support for a January 1, 2009 compliance date to also supply specific evidence and data regarding industry readiness or ability to be ready.

The Board will likely schedule time during its March 25, 2008 meeting, or during any subsequent meeting of the full Board, to receive oral testimony or presentations regarding any of the written submissions it receives prior to the January meeting or any subsequent meeting of the full Board. This may depend in part on the submissions.