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Food and Drug Administration:

We have serious concerns about the proposed storage requirements for fresh frozen plasma and cryoprecipitates change. We maintain two separate stock storage freezers for our patient population here in our university medical center transfusion service. These normally run at -30° with a defrost cycle up to -27°. We can set the alarm points at -26°, but this gives us only 2° leeway for fluctuations. If our freezers unexpectedly vary to warmer than -25°, we would be faced with the challenge of removing all of the stock, editing the expiration date, and potentially needing a third freezer to separate this modified stock from those with a full year expiration. Maintaining a separate stock with a 3-month expiration might lead to errors in labeling and in dispensing. Changing all the expiration dates in the computer would be very time consuming, and without making the change, we emphasize: there would be a great potential for issue errors.

Please make this regulatory change only if it is in the absolute best interest of the patient; we will make the appropriate changes to assure component integrity.

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