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Comment On: FDA-2014-N-1960-0001
Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

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Comment from NAVDEEP SOMANI, NA

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General Comment

1. In Section A1: Along with Patient Identifier, in bracket (first, last) can be added for better identification.
2. In Section A2, Age group can be added.
3. In Section A3, after selecting Female, a check box should populate for pregnancy with options Yes, No, UNK. Pregnancy can be removed from section B7.
4. In Section B1, if Product problem check box is selected then only a text box to enter NDC# should come as National drug code is required ONLY when reporting a drug product problem. It can be removed from C9.
5. In section B2, Hospitalization - initial or prolonged can be relabeled to only Hospitalization and can have three check boxes; Initial, Prolonged and Hospital discharge summary available. Reporter can select whichever is applicable.
6. In section B5, Describe Event or Problem, along with individual event terms, seriousness criteria for each event should be populated, so that event wise seriousness criteria can be identified.
7. Action taken with drug can be added in section C.
8. Causality scale can be added in Section C.
9. In section C10, Concomitant Medical Products and Therapy Dates (Exclude treatment of event), Dose of concomitant drugs should also be included.
10. In Section E1, along with Phone#, Email address can also be included.