How MedSun Works:

Hospitals, nursing homes, and other healthcare facilities are currently required to report serious medical device-related adverse events (those that result in serious illness, injury, or death) to CDRH under the Safe Medical Devices Act (SMDA). Reporting through MedSun about such events fulfills this statutory requirement. MedSun helps those charged with reporting by providing a secure, on-line system that is based on the MedWatch Form 3500A that is currently used for SMDA reporting. Reporting serious medical device events to the MedSun system fulfills a facility's SMDA requirements. MedSun also provides options to capture additional information (e.g. voluntary reports about close calls and safety concerns for particular devices) that can help improve the safe and effective design and use of medical devices.

Our MedSun contractor, Social &Scientific Systems (SSS) provides reporting assistance, processes the reports submitted by participating sites, and subsequently releases the reports to the FDA and manufacturers. SSS supplies MedSun participants with feedback concerning the reports through monthly e-mail and website newsletters, as well as information about product recalls and new technology. MedSun representatives are eligible for participation in periodic conference calls about topics of interest about the use of medical devices and patient safety (e.g., recent calls concerning electromagnetic interference and alarm safety). They may also request searches of the FDA device problem database, and receive training materials concerning how to recognize and investigate device-related incidents and posters to promote reporting of problems with medical devices.

MedSun is an important part of CDRH's post-market surveillance effort. Our primary goals for MedSun are to prevent serious injuries and deaths by obtaining better data on problems with medical devices than is currently available and to establish two-way communication with the clinical community so we may better understand the problems with the use of medical devices. CDRH and manufacturers have taken a number of important patient safety actions for the benefit of public health in the nation as a result of MedSun reports received to date, including withdrawal of a particular surgical gel from the market and providing hospitals and OB/GYN physicians with information about problems with the use of certain syringes used for amniocentesis procedures; and a dialysis device.

What Does Participation Involve?

Participating hospitals must agree:

a) to have a Risk Manager and a Biomedical or Clinical Engineer designated to report to the project as MedSun Representatives (other persons, such as OR Managers, Materials Management Directors and Patient Safety Officers, may be included on the team as well), and participate in a MedSun orientation session as described below, and

b) to make a bona fide effort to report on any serious medical device adverse events and situations indicating potential for harm from medical devices that have been observed at the hospital for a 1-year period using MedSun's secure, on-line reporting system. (Reporting through the MedSun project about serious events takes the place of the regular reporting non-MedSun hospitals are required to provide according to the Safe Medical Devices Act.)

In addition, from time to time, we ask that MedSun hospitals provide, on a voluntary basis, **information from medical specialists responding to "rapid response" surveys** or other data collection about their **experiences with medical devices of interest to FDA analysts** such as has been done for vena cava filters (for Interventional Radiologists) and for drug-eluting stents (for Directors of Cardiac Catheterization Laboratories). Feedback is provided to the extent possible after these data collection efforts.

Orientation sessions for the Risk Managers, Biomedical Engineers and others who will be designated as hospital MedSun Representatives will be oriented through web cast training sessions.

Benefits of the Project for Participating Hospitals

In addition to fulfilling their SMDA reporting requirements through their reports, MedSun members also appreciate learning about the experiences of all the healthcare facilities (without identification) that participate in the MedSun project through our monthly newsletter. MedSun Representatives will also receive additional services, including:

- CDRH alerts, advisories and recall notices immediately after release;
- The ability to request special analyses of the MedSun database, as well as FDA's Manufacturer and User Facility Device Experience (MAUDE) database;

Other Benefits Include:

- No need to submit paper MedWatch 3500A forms. Instead, you may use the MedSun secure network to submit required reports to CDRH and manufacturers.
- No need to look up codes in the MedWatch manual. MedSun staff will complete all the required coding for your reports and will assist in preparation of your annual report to the FDA.
- Online access to all your submitted reports at any time during the project period.
- Training materials that you can use for your staff, such as slide presentations for audiences such as nurses and laboratory personnel, designed to encourage staff to report adverse medical device events to you.
- Materials from periodic MedSun Clinical Engineering audio conferences and our Electrosurgery Safety Workshop.
- Educational programs for hospital staff with continuing educational credits (CEU's) awarded through the California Nurses Association.

For additional information, see our website at https://www.medsun.net or call 1-800-859-9821.