



NATIONAL HEMOPHILIA FOUNDATION

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MASAC Document #229
(Replaces Document #94)

MASAC RESOLUTION REGARDING CONSUMER PARTICIPATION IN THE NATIONAL PATIENT NOTIFICATION SYSTEM

This document was approved by the Medical and Scientific Advisory Council (MASAC) on September 20, 2014, and adopted by the NHF Board of Directors on September 21, 2014.

The National Hemophilia Foundation is a vigilant advocate for the safety of the nation's blood and plasma products and derivatives. MASAC supports the maintenance of the Patient Notification System (PNS), established by the PPTA, which is a voluntary notification system for reporting problems with plasma-derived and recombinant clotting factor products. MASAC acknowledges that the PNS is an important public health initiative and an essential effector mechanism of the existing systems of blood surveillance and safety. The PNS currently includes approximately 6000 registrants, which is estimated to include less than 5% of the nation's consumers of plasma-derived therapies. MASAC is concerned that the voluntary notification system has not been effectively promoted to the bleeding disorders community, including consumers and caregivers.

MASAC has previously identified participation in the PNS as one of the Standards of Service for pharmacy providers of clotting factor concentrates for home use to patients with bleeding disorders. (MASAC Recommendation #188). Pharmacy providers, hemophilia treatment centers, and distributors of plasma products and recombinant clotting factors should consider it a best practice to inform consumers about the notification system and to educate consumers that the PNS is an essential component of hemovigilance and that the effectiveness of the voluntary warning system is directly related to enrollment.

Privacy and confidentiality need to remain of paramount importance. MASAC recommends that consumers enroll in this direct notification system as the quickest and most direct way of being notified of any recalls involving product that they might have in their possession but have not yet used. The healthcare team providing care for the individual with a bleeding or clotting disorder should discuss registration in the PNS as a part of the comprehensive care visit. The discussion should include whether registrant's contact data in PNS remains current and any potential barriers to notification (including potential language and technology barriers).

MASAC urges NHF to consider how to partner with advocacy groups for consumers of blood component-derived therapeutic agents for conditions beyond bleeding and clotting disorders to achieve maximum penetration of PNS registration among all individuals exposed to plasma components.

Registration in PNS is accomplished via the following link: <http://www.patientnotificationsystem.org/>

This material is provided for your general information only. NHF does not give medical advice or engage in the practice of medicine. NHF under no circumstances recommends particular treatment for specific individuals and in all cases recommends that you consult your physician or local treatment center before pursuing any course of treatment.

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