



PSBC introduces new therapeutic phlebotomy policies July 8, 2013

In August 2012, PSBC undertook a comprehensive review of its protocol and medical policies for people with conditions treated by blood collection -- known as "therapeutic phlebotomy" (TP). Since that time all people with conditions that are (or may) be treated by TP have been deferred as voluntary blood donors to the community blood supply through the normal collection process, including mobile drives. In the meantime, PSBC's Therapeutic Phlebotomy Program continued to provide TP treatment at its 11 donor centers for people who require blood withdrawals prescribed by their health care provider.

PSBC's goal and responsibility is to fulfill its mission as a non-profit but financially sustainable partner in health care with 70 hospitals and treatment centers in the region. To do that in today's health care environment, PSBC must take into account the resources and expenses associated with drawing patients in its TP program by appropriately billing for these medical services at rates that will recover the costs involved.

Effective July 8, 2013 our TP policies will be updated to reflect compliance with federal regulations, including rigorous verification of a person's diagnosis and the medical necessity for all TP treatments performed at PSBC centers. PSBC will achieve fair recovery of costs for TP treatments in order to be able to provide this service to the patients in need of it.

- A. Therapeutic phlebotomy: compliance requirements**
- B. TP donations from people with hereditary hemochromatosis (HH)**
- C. PSBC Therapeutic Phlebotomy Program (effective July 8, 2013)**
- D. Thank you for your understanding**

A. Therapeutic phlebotomy: compliance requirements

Federal regulations and accreditation requirements of the College of American Pathologists require that all TP treatments be supported by a current order from an individual's health care provider. In providing TP, PSBC must also undertake a diagnostic review for each patient to determine whether the treatment meets the criteria of medical necessity as defined by certification authorities and third party insurance providers, including Medicare. Meeting these responsibilities results in measureable expenditures that reflect the actual costs incurred in providing patients with TP treatment services.

There is strong medical support for TP for people with hereditary hemochromatosis (iron accumulation or overload), non-genetic hemochromatosis, and polycythemia vera (PV) related to marrow overproduction of red cells. Most secondary polycythemia conditions from heart disease, testosterone administration, and others have weaker medical supporting data for the

procedure, although the referring physician may order TP in hope of improving the patient's condition.

B. TP collections from people with hereditary hemochromatosis (HH)

In 2003, the Food and Drug Administration (FDA) issued an 'exception' policy that allowed TP collections from people diagnosed with HH to be eligible for inclusion in the community blood supply under certain stringent conditions. PSBC gratefully received many donations from community-minded and dedicated HH donors during the period between 2003 and 2012.

Over the past eight months, PSBC thoroughly reviewed its program for obtaining blood from HH donors for use in the community supply. A review of records showed considerable variability in approaches by health care providers – raising concern that HH patients were not consistently distinguished from patients with other, non-genetic causes for iron deposition whose TP collections are not eligible for inclusion in the community supply. We determined that we could no longer use therapeutic donations for the community supply.

PSBC's goal and responsibility is to fulfill its mission as a non-profit but financially sustainable partner in health care with 70 hospitals and treatment centers in the region. To do that in today's health care environment, PSBC must take into account the resources and expenses associated with drawing patients in its Therapeutic Phlebotomy program by appropriately billing for these medical services at rates that will recover the costs involved.

In order to recover the costs associated with clinical staff, materials, resources and required medical oversight, charges for TP procedures must in fairness be applied all patients requiring TP.



C. PSBC Therapeutic Phlebotomy Program (effective July 8, 2013)

1. All people needing blood to be drawn as treatment for a diagnosed medical condition must have a valid order from their licensed health care provider -- including those with genetic predisposition to iron overloading (hereditary hemochromatosis, or HH).
2. PSBC has concluded that the medical oversight, complexity, safeguards and risks associated with receiving HH donations into the community blood supply make these collections impractical, and result in costs that are prohibitively high. We do not anticipate that HH donations will be eligible for inclusion in the community blood supply in the foreseeable future.
3. All TP treatments performed by PSBC require that referring physicians complete a Therapeutic Phlebotomy Packet available at psbc.org/therapeuticphlebotomy. This packet includes: an order form based on patient diagnosis, consent form, billing form, Advance Beneficiary Notification (ABN) form, and request for supporting documentation such as lab test results or patient records.
 - **New TP orders:** (after 07/08/2013): referring physician is required to complete the TP Packet before treatment begins.
 - **Existing TP orders:** referring physician must update order by 09/02/2013, with the TP Packet completed, for treatment to continue. TP orders issued prior to 07/08/13 will be honored until their expiration, or until 09/02/2013 -- whichever date occurs first. After 09/02/2013, all TP treatments at PSBC must be backed by TP Packets completed by the referring physician in order for treatment to take place.
4. PSBC medical staff must receive, review and approve all TP orders and supporting documentation from the TP packet in advance, before treatment commences. All TP orders expire after one year, and must be re-submitted and reviewed by PSBC medical staff.
5. People with TP orders that have been reviewed and approved by PSBC medical staff can receive those treatments by appointment during regular center hours Monday through Friday at any one of PSBC's 11 donor centers across Western Washington (list attached). TP treatment is not available at mobile blood drives.
6. All TP treatment performed at PSBC centers is subject to cost recovery through the patient's insurer or from the patient. The cost per TP treatment will be \$103.00.



7. Additional safeguards are being implemented to confirm that lab results, condition diagnosis, treatment protocols and medical necessity guidelines meet the established consensus of medical experts. These updated policies and practices are consistent with appropriate medical practice.

D. Thank you for your understanding

We appreciate the understanding of those impacted that these changes are driven by a need to ensure the maximum benefit from community dollars invested in health care, and to fairly recover costs for medical treatments that PSBC provides. The updated policies also reflect diligence to do our utmost to ensure the safety of the community blood supply.

To people with hereditary hemochromatosis: we sincerely appreciate your donations over the past ten years, which benefited countless people in need of blood. We hope any disappointment you feel will not discourage your valued support for PSBC and its commitment to save lives through research, education and excellence in blood, medical and laboratory services in partnership with our community.

To prescribing physicians and patients needing or receiving TP treatment at PSBC centers: we look forward to continuing to serve your needs for therapeutic phlebotomy, and providing you with the highest quality patient care.

Rebecca Haley, MD
Medical Director, Therapeutic Phlebotomy Program



Donor Centers Providing Therapeutic Phlebotomy Treatment

Select the most convenient donation center for a map and driving directions. You can make an appointment by calling 1-800-398-7888. **When calling, please ask for the Therapeutic Department.**

- [Bellevue Center](#)
1021 112th Avenue NE
Bellevue, WA 98004
425-453-4011
- [Bellingham Center](#)
1125 E Sunset Drive
Bellingham, WA 98226
360-671-8848
- [Central Seattle](#)
921 Terry Avenue
Seattle, WA 98104
206-292-6500
- [Everett Center](#)
2703 Oakes Avenue
Everett, WA 98201
425-740-2909
- [Federal Way Center](#)
1414 S 324TH Street
Suite B101
Federal Way, WA 98003
253-945-8660
- [Lynnwood Center](#)
19723 Highway 99, Suite F
Lynnwood, WA 98036
425-412-1000
- [Olympia Center](#)
1220 Eastside Street SE
Olympia, WA 98501
360-352-1100
- [North Seattle Center](#)
10357 Stone Avenue N
Seattle, WA 98133
206-526-1970
- [Silverdale Center](#)
3230 NW Randall Way
Silverdale, WA 98383
360-308-7340
- [Tukwila Center](#)
130 Andover Park E
Tukwila, WA 98188
206-241-6300
- [Vancouver, WA Donor Center](#)
Southwest Washington Blood Program
9320 NE Vancouver Mall Blvd, Suite 100
Vancouver, WA 98662
360-567-48