

**Clarification of PSI Advisory Opinion, No. 02-01, as Modified
in March 2017**

As part of the settlement of *Patient Services, Inc. v. United States of America*, et al., 3:18-cv-00016 (E.D. Va.) (MHL), the U.S. Department of Health and Human Services Office of Inspector General (“HHS-OIG”) provides the following clarifications. Such clarifications are limited to addressing the alleged restrictions described in paragraph 129 of Plaintiff’s Complaint in the above-referenced case. This document is incorporated by reference in the Settlement Agreement in the above-referenced case and has no force or effect prior to the Effective Date of the Settlement Agreement.

Clarifications

HHS-OIG does not interpret communications by PSI with donors or prospective donors on the following topics as inconsistent with the certifications on which the March 2017 modification to Advisory Opinion 02-01 is based:

- (i) the number of individuals affected by a particular disease state
- (ii) the demographics (including expected financial resources) of the patient population
- (iii) the availability and cost of treatments, such as co-payments, deductibles, and premiums, including any new treatments in the developmental pipeline
- (iv) the expected utilization of drugs or other treatments to treat a disease state
- (v) coverage and other restrictions that payors are likely to impose, including, where applicable, government payors
- (vi) the likely duration of therapy
- (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home)
- (viii) any ancillary patient needs such as transportation services
- (ix) assistance for other supportive therapies that may be necessary
- (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug
- (xi) the costs associated with addressing side effects of the drugs or treatments

These clarifications do not apply to any other communications or conduct or otherwise alter the certifications upon which the March 2017 modification to Advisory Opinion 02-01 is based.