

# PUBLICATION

---

## Jury Verdict Against Millennium Provides Insight on Definition of Remuneration [Ober|Kaler]

July 03, 2014

**Ameritox won the latest volley of an ongoing legal battle with Millennium when a federal jury in Florida awarded it \$14.75 million on June 16, 2014. Ameritox persuaded the jury that Millennium's free point of care test (POCT) cup program violated the federal Stark law and antikickback law (AKS) and therefore constituted unfair competition and tortious interference with Ameritox's business relationships in four states.**

POCT cups are urine test cups containing a number of reagent strips that provide immediate qualitative testing for various drugs of abuse. They are used frequently in drug and alcohol rehabilitation and pain management settings. Physicians using POCT cups can perform urine tests and bill the patient's insurer for those tests. Reimbursement rates vary and can be as high as several hundred dollars. Since the POCT results are only qualitative, specimens are often forwarded to toxicology laboratories such as Millennium for confirmatory quantitative testing. Such testing can be highly remunerative for the laboratory.

Under Millennium's free cup program, physicians would receive free POCT cups only if they agreed not to bill for the use of the POCT cup, used the POCT cup solely for an initial indication on a urine test, and transported the sample in the POCT cup to Millennium for testing.

Under the federal Stark law, a physician cannot refer Medicare or Medicaid patients to a clinical laboratory if the physician has a financial relationship with that laboratory. Inherent in the definition of *financial relationship* is that remuneration, or something of financial value, be exchanged. There is an exception to the statutory definition of *remuneration* that permits the provision of items used *solely* to collect, transport, process, or store specimens or to communicate the results of tests. The AKS prohibits health care providers from knowingly and willfully offering, soliciting, paying or receiving remuneration in exchange for referrals of services paid for by a federal health care program. OIG guidance similarly permits sole use collection devices.

In its suit filed in 2011, Ameritox alleged that Millennium had given the physicians remuneration which resulted in an impermissible financial relationship because (1) the POCT cups had value; (2) Millennium gave the cups to physicians for free; and (3) the POCT cups were used not just for collection and transport, but also for actual testing.

In May 2014 the court ruled on partial summary judgment that Millennium's practice of giving free POCT cups to physicians was remuneration under both the federal Stark law and the AKS and was not protected by any statutory or regulatory exception, in those instances where physicians were precluded from billing for the POCT tests for reasons other than the agreement with Millennium. The court left to the jury the question of whether the agreement not to bill took the POCT cups outside the definition of *remuneration*. In June the jury clearly concluded that the cups were remuneration and rendered its verdict for Ameritox.

## Ober | Kaler Comments

This outcome is hardly surprising. The POCT cups quite clearly had value to the referring physicians, notwithstanding Millennium's protestations to the contrary. One suspects that the jury's ruling was driven by the fact that Millennium could not answer one fundamental question: If the POCT cups had no value, why was it so important to provide them? To the jury, it did not matter if the physician gave up a future right to bill or not – the distribution of the POCT cups was remuneration whether the physician could – or could not bill. It would appear that Millennium's legal woes are just beginning. The case quite clearly finds Stark and AKS violations that put Millennium's entire government revenues in jeopardy.