UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *ex rel.* RICHARD TEMPLIN AND JAMES BANIGAN, *et al.* Plaintiffs, vs. ORGANON USA INC., *et al.*, Defendants.	Civil Action No. 07-12153-RWZ LEAVE TO FILE GRANTED OCTOBER 7, 2016

REPLY IN SUPPORT OF OMNICARE, INC.'S MOTION TO RECONSIDER THE COURT'S AUGUST 23, 2016 ORDER OR, IN THE ALTERNATIVE, TO CERTIFY THE MATTER FOR INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

Omnicare respectfully submits this reply brief in order to correct the two unfounded assertions that are the bases of Relators' opposition to Omnicare's request for certification for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).[1]

First, contrary to what Relators assert in their opposition, whether the regulatory discount safe harbor ("RDSH") required Omnicare affirmatively to provide the discount and rebate contracts at issue to the Department of Health and Human Services ("HHS") even in the absence of any agency request is a pure, dispositive question of law. There is no material dispute about the facts: Omnicare never refused to comply with any HHS request to inspect its Remeron discount and rebate contracts, and indeed HHS never made such a request. The only dispute is about how to interpret the second prong of the RDSH. Relators argue that the RDSH's second prong always requires the recipient to provide HHS with a copy of the discount or rebate contract, whereas Omnicare argues that it requires the recipient to do so *only if* HHS makes a

[1] In the interests of brevity, Omnicare respectfully stands on its Opening Brief with respect to its request for reconsideration.

request for the information. If this issue of regulatory interpretation is resolved in Omnicare's favor, Relators' case will be at an end: the Court rightly concluded in its August 23, 2016 Order that the discount and rebate contracts at issue satisfied the first prong of the RDSH, *see* Opening Br. at 14 (citing page 9 of the Court's Order), and if the First Circuit Court of Appeals agrees with Omnicare's reading of the second prong of the RDSH, the only conclusion will be that the RDSH was satisfied here and therefore that the discounts and rebates at issue did not violate the Anti-Kickback Statute. As Relators conceded at oral argument, that holding would end Relators' False Claims Act claims.[2]

Second, contrary to what Relators argue in their opposition, this dispositive question of regulatory interpretation is, at the very least, a reasonably debatable one. The first and most important canon of statutory and regulatory interpretation is that "a court should interpret a regulation so that, 'if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" *Morales v. Sociedad Espanola de Auxilio Mutuo y Beneficencia*, 524 F.3d 54, 59 (1st Cir. 2008) (quoting *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001)). Under the Court's interpretation of the RDSH's second prong, the obligation of the buyer (here, Omnicare) to provide a copy of the discount or rebate contract to HHS is not conditioned on the buyer having received a "request by the Secretary or State agency" for that information. The Court's construction of the RDSH's second prong therefore conflicts with the core canon of construction that the First Circuit reiterated in *Morales* because it reads an entire clause — ", upon request by the Secretary or a State agency," — out of the RDSH's second prong, 42 C.F.R.

[2] Relators argue in their opposition that Omnicare's reading of the RDSH protects discounts and rebates that are "fraudulent and illegal." Opp. at 1. If a discount or rebate satisfies the RDSH, however, it is by definition not unlawful remuneration under the Anti-Kickback Statute and thus is *legal*. Furthermore, Relators offer no explanation for why or how a discount or rebate is "fraudulent" where (i) the terms of the discount or rebate are reduced entirely to writing in advance, and (ii) the recipient of the discount or rebate retains a copy of the contract, which HHS can request and inspect if it pleases.

§ 1001.952(h)(1)(iii)(B). By contrast, Omnicare's interpretation of the RDSH's second prong gives full operative effect to that clause, and it does so without any ill effects to HHS's interests because HHS is able to review any discount or rebate agreement simply by making the "request" that the RDSH contemplates.

Although Relators argue that their interpretation of the RDSH's second prong finds support in out-of-context HHS rulemaking commentary from 1991 — eight years before HHS issued its "clarification of the initial [ ] safe harbor provisions," 64 Fed. Reg. 63,518, 63,529 (Nov. 19, 1999), which made clear that a charge-based provider's obligation to disclose the rebate to HHS "upon request of the Secretary" is *not* an obligation to "disclose the . . . discounts" proactively in the absence of a request, *see, e.g.*, Opening Br. at 7-8 — this does not remotely eliminate the existence of a reasonable debate about how the RDSH's second prong should be construed.[3]

The legal issue for which Omnicare is requesting certification for interlocutory appeal is not only a dispositive one here, but it is also an issue that has substantial importance to the healthcare industry more broadly. Each year, drug and device manufacturers provide billions of dollars in rebates to charge-based healthcare providers reimbursed by Medicare and Medicaid. Congress and HHS have recognized that these discounts and rebates benefit the healthcare system as a whole, reducing costs indirectly even when they are not immediately passed through

[3] The 1991 rulemaking commentary cannot bear the weight that Relators place on it. Relators flatly ignore portions of the 1991 commentary that undermine their interpretation of the RDSH's second prong. For example, in discussing a substantially-similar "upon request" provision applicable to cost-report providers, the OIG stated that a cost-report buyer must provide HHS with "appropriate invoices from the seller" that reflect the extent of the discount "*if* the Secretary or a State Medicaid agency requests [that] information . . . ." 56 Fed. Reg. 35,952, 35,979 (July 29, 1991) (emphasis added). Thus, it is clear that even in its 1991 rulemaking the OIG contemplated that disclosure to HHS of the discount or rebate contract is required only *if* a request is made by the government.

to the government.[4] The ability of manufacturers to offer and charge-based providers to accept these discounts and rebates largely, if not entirely, depends upon the availability of the RDSH. Under the Court's interpretation of the RDSH's second prong, it would seem that all of these discounts and rebates are presumptively illegal.[5] In fact, in response to the Court's Order, two experienced healthcare law experts expressed concern that the Court's interpretation of the RDSH's second prong "eviscerates the safe harbor, rendering it virtually useless" to charge-based providers.[6]

In sum, the dispositive legal issue of whether the Court correctly interpreted the RDSH's second prong is critically important to the healthcare industry as a whole and ripe for appellate

[4] *See, e.g.*, 64 Fed. Reg. 63,518, 63,529 (Nov. 19, 1999) ("[W]e have concluded that excluding safe harbor protection for all rebates to charge-based buyers or buyers that are reimbursed based on Federal program fee schedules[, who do not directly pass through to the government the rebates they receive,] is unnecessarily restrictive and may prevent the Federal health care programs from realizing indirect benefits that may accrue from rebates to charge-based providers.").

[5] Relators argue that, rather than waiting for HHS to request a copy of the rebate contract, Omnicare could have proactively mailed a copy of the rebate contract to HHS, perhaps as part of a request that OIG issue Omnicare an advisory opinion. As an initial matter, the RDSH does not contain any such proactive disclosure requirement. This is for good reason: such a requirement would be utterly impractical and unworkable. At any one time, there are likely tens if not hundreds of thousands of in-force discount and rebate agreements involving charge-based providers, as well as a similar number of new discount and rebate agreements under negotiation. If, as Relators suggest, every charged-based provider were required to disclose to HHS proactively all of its discount and rebate agreements, HHS would soon find itself deluged with copies of these contracts and advisory opinion requests. HHS would have to dedicate substantial agency resources just to handle the enormous burden of all the incoming mail. The RDSH's language regarding the provision of the contracts "upon request" demonstrates that there was no intention to saddle HHS with the burden of receiving, let alone reviewing, contracts that it never requested. Regardless, it would be an odd result to judicially eliminate a safe harbor provision — which Relators seem not to contest is the practical result of the Court's Order — because of the theoretical, if impractical, availability of an alternate means to obtain protection.

[6] "Massachusetts District Court Guts Discount Safe Harbor," FDA Law Blog, S. Schlanger & A. Kirschenbaum, *available at* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/09/massachusetts-district-court-guts-discount-safe-harbor-.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+FdaLawBlog+%28FDA+Law+Blog%29 (last visited Sept. 16, 2016).

resolution. The issue is at least a debatable one, and the First Circuit should be given the chance to address it now.[7]

CONCLUSION

For the reasons stated above and in Omnicare's Opening Brief, if the Court does not reconsider its summary judgment decision, Omnicare's request for certification under 28 U.S.C. § 1292(b) should be granted.

Dated: October 7, 2016

Respectfully submitted,

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[7] If the Court does not grant interlocutory certification, the First Circuit might never have the opportunity to address the issue, because the jury may resolve the case in Omnicare's favor on some other element of the False Claims Act, such as scienter.

CERTIFICATE OF SERVICE

I hereby certify that the above document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and that paper copies will be sent to those indicated as non-registered participants on October 7, 2016.

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