

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

<b>PUBLIC CITIZEN, INC.,</b>	:	
	:	
<b>Plaintiff,</b>	:	
	:	
v.	:	<b>Civil Action No. 00-0731</b>
	:	<b>(ESH)</b>
<b>DEPARTMENT OF HEALTH AND,</b>	:	
<b>HUMAN SERVICES, <i>et al.</i>,</b>	:	
	:	
<b>Defendants.</b>	:	

**MEMORANDUM OPINION**

Plaintiff Public Citizen, Inc. has sued the Department of Health and Human Services (“HHS”) and the Health Care Financing Administration (“HCFA”) under the Administrative Procedures Act (“APA”). Plaintiff alleges that HCFA’s regulations and its Peer Review Organization Manual (“PRO Manual”), which prohibit disclosure by a PRO of the final disposition of its investigation of a complaint brought by a beneficiary of the Medicare system if that information identifies a practitioner who does not consent to disclosure, are contrary to the Peer Review Improvement Act of 1982, 42 U.S.C. § 1320c, *et seq.* Defendants respond that the maintenance of the confidentiality of such information absent practitioner consent is both consistent with the statute and necessary to a PRO’s ability to perform its duties and to evaluate doctors who have been the subject of a beneficiary complaint. Both parties have moved for summary judgment. Based on the pleadings and the entire record herein,<sup>1</sup> the Court grants plaintiff’s motion for summary judgment, and denies defendants’ motion.

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<sup>1</sup> At the Court’s request, defendants supplemented the administrative record after the briefing of these motions to submit sample materials prepared by a PRO in its investigation.

## BACKGROUND

Plaintiff Public Citizen has brought this suit on behalf of its members, and specifically on behalf of member David Shipp, who had initiated a PRO complaint regarding the care of his wife Doris Shipp. On December 15, 1998, Mrs. Shipp went to Baptist East Hospital in Louisville, Kentucky complaining of abdominal pain. (R. 2.) Over the next few months, Mrs. Shipp was seen by Dr. Peter Thurman, Dr. Thomas C. Dedman, and Dr. David Jolgren. (Id.) Mrs. Shipp died of cancer in June, 1999. (R. 1.) On December 6, 1999, Mr. Shipp wrote a letter to Health Care Excel, the PRO responsible for monitoring the delivery of Medicare services in Kentucky, and requested that the PRO investigate and respond to his concerns about the quality of care his wife had received. (Id.) Mr. Shipp also submitted a consent form which acknowledged “[i]f you request a final response which discusses the outcome of our review, the involved doctor may not give us permission to release our review findings to you. In that case, you will receive only the general notice that the review has been completed.” (R. 4.)

On August 7, 2000, the PRO sent Mr. Shipp three letters. One letter reported that the PRO had completed its investigation of the health care services provided by Dr. Thurman, and concluded that “[n]o quality of care issues were identified with the services provided by Dr. Thurman. It has been determined that the examination your wife received on March 24, 1999, was appropriate and not expected to reveal the cecal cancer diagnosis that was later discovered.” (R. 9.) Dr. Thurman apparently consented to the release of that information, which as discussed below, under the relevant HCFA regulations would not be released without his consent.

A second letter addressed Mr. Shipp’s complaints regarding Dr. Dedman. (R. 5.) This letter reported that “[b]efore providing this response, we gave Dr. Thomas Dedman an opportunity to review the information and provide comments.” (Id. (emphasis in original)). The

letter informed Mr. Shipp:

We have carefully examined all the issues raised in your correspondence and conducted a thorough review of the care your wife received. Federal laws and regulations prohibit us from releasing information about your care without the consent of your physician. Your wife's physician did not give consent; therefore, we are unable to provide any specific information about the results of our review. Our inability to provide this information does not mean that we found any problem with the care she received. However, please be assured that if we did find a problem, we will take all necessary action when our review findings warrant it.

(Id.) The letter concerning Dr. Jolgren also reported that Dr. Jolgren did not consent to the release of information concerning his care of Mrs. Shipp, and provided this same explanation.

(R. 7.)

### **STATUTORY FRAMEWORK**

The Peer Review Improvement Act of 1982 created the Medicare Utilization Quality Control Peer Review Organization Program (“PRO program”) to oversee the administration of health services provided under Medicare. Under the PRO program, HCFA, an agency within HHS, contracts with private organizations composed of licensed physicians to provide peer review services to the government. See 42 U.S.C. § 1320c-2(b) (West 1991). The PROs review health care services provided under Medicare to insure that they are reasonable and medically necessary, and that the quality of the services meets the appropriate standard of care. See 42 U.S.C. § 1320c-3(a)(1) (West Supp. 2000). PROs must comply with the Peer Review Improvement Act and the implementing HCFA regulations, as well as the contract governing the relationship between the PRO and HCFA. HCFA has also issued a PRO Manual. (See R. 11-29.) Under the Act, PROs are required to investigate complaints made by Medicare beneficiaries and their representatives about the quality of care given by a Medicare funded provider. 42 U.S.C. § 1320c-3(a)(14) (West Supp. 2000) (PROs “shall conduct an appropriate review of all

written complaints about the quality of services . . . not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such subchapter . . .”). The statute further provides that “[t]he organization shall inform the individual (or representative) of the organization’s final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.” 42 U.S.C. § 1320c-3(a)(14) (emphasis added). It is this provision which is at issue here.

The statute also provides that “[a]ny data or information acquired by [a PRO] in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person” except under certain delineated circumstances (42 U.S.C. § 1320c-9(b)), as well as “to the extent that may be necessary to carry out the purposes of this part.” 42 U.S.C. § 1320c-9(a)(1) (West Supp. 2000). However, the disclosure of information is also permitted “in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.” 42 U.S.C. § 1320c-9(a)(2) (West Supp. 2000). In addition, the statute permits the disclosure of information, in accordance with certain safeguards and procedures, “which may identify specific providers or practitioners as may be necessary” to assist Federal and State agencies with responsibility for investigating cases of fraud or abuse, identifying public health risks, and licensing and certification of health care providers. 42 U.S.C. § 1320c-9(b)(1) (West Supp. 2000). Finally, certain materials are exempt from discovery in civil legal proceedings:

No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an

organization in connection with its deliberations in making determinations under section 1320c-3(a)(1)(B) or 1320c-5(a)(2) of this title shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's findings and conclusions in making the determination.

42 U.S.C. § 1320c-9(d) (West Supp. 2000).

Under regulations promulgated by HCFA pursuant to the delegation in 42 U.S.C. § 1320c-9(a)(2), HCFA defines “confidential information” to include “(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer; (2) Sanction reports and recommendations; (3) Quality review studies which identify patients, practitioners or institutions; (4) PRO deliberations.” 42 C.F.R. § 480.101(b) (2000). Under the regulations, “[i]mplicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.” *Id.* The regulations incorporate the statutory bases for disclosure of confidential information enumerated in § 1320c-9(a) and (b). 42 C.F.R. § 480.103 (2000).<sup>2</sup> The regulations also provide that “[a] PRO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.” 42 C.F.R. § 480.133(a)(2)(iii) (2000) (emphasis added). These regulations were issued on April 17, 1985, and became effective on May 17, 1985. A year after these regulations were promulgated, Congress amended the Act in October 1986 to require PROs to investigate all beneficiary complaints about quality of care, and to report to the beneficiary “the organization’s

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<sup>2</sup> The regulations also detail the permissible disclosures of non-confidential information, 42 C.F.R. § 480.120-121, and enumerate permissible disclosures of confidential information in addition to those contained in § 1320c-9. 42 C.F.R. § 480.130-143. None of these regulatory provisions provides a basis for the type of disclosure at issue in this case.

final disposition of the complaint.” 42 U.S.C. § 1320c-3(a)(14).<sup>3</sup>

Pursuant to the regulations it had promulgated prior to the enactment of § 1320c-3(a)(14), defendants have applied this provision to prohibit the disclosure of information which identifies a practitioner without that practitioner’s consent.<sup>4</sup> Plaintiff argues that § 1320c-3(a)(14) requires PROs to inform a beneficiary complainant whether quality of care issues were identified as to a particular practitioner and that HCFA regulations prohibiting such disclosure are contrary to the statute. Plaintiff contends that the intent of Congress in enacting the amendment in 1986 to require a PRO to disclose to the beneficiary the result of its investigation is clear and unambiguous, and notwithstanding the delegation of authority to HHS to implement regulations with respect to confidentiality, disclosure is required by § 1320c-3(a)(14) and permitted by 42 U.S.C. § 1320c-9(a)(1), which provides that a PRO may disclose information “to the extent that may be necessary to carry out the purposes of this part.” Plaintiff also contends that even if the statute is found to be ambiguous, defendants’ interpretation is unreasonable.

Defendants respond by arguing that § 1320c-3(a)(14) should be interpreted to require

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<sup>3</sup> Prior to this amendment, the statute provided that “[t]he [peer review] organization shall review some or all of the professional activities in [its] area . . . of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part)” under Medicare, to determine whether such services were reasonable and medically necessary, of a quality that met professionally recognized standards of health care, and, in the case of hospital inpatient services, whether those services could be more economically provided on an outpatient basis or in another inpatient setting. 42 U.S.C. § 1320c-3(a)(1) (West Supp. 2000). Apparently, prior to the enactment of § 1320c-3(a)(14), PRO’s could choose to review beneficiary complaints, pursuant to this section’s mandate that it review “some or all” services. Section 1320c-3(a)(14) requires PRO’s to review the services at issue in a beneficiary complaint.

<sup>4</sup> The PRO Manual sets forth HCFA’s policy that information that identifies a practitioner is confidential and cannot be included in the response to a beneficiary complaint without consent. (R. 11-23.)

“only that PROs inform beneficiary complainants that their complaint was received, that it was investigated, and that corrective action was taken if appropriate.” Def. Cross Mot. at 20.

Defendants further contend that Congress intended that practitioner-identifying information be disclosed only where expressly permitted by the statute in § 1320c-9(b), or where the Secretary, in promulgating regulations governing confidentiality and disclosure of information under the statute, has determined such disclosures to be justified. Defendants therefore argue that the regulations prohibiting disclosure of practitioner-identifying information are consistent with § 1320c-3(a)(14). Alternatively, defendants argue that the statute is ambiguous in what is meant by “the final disposition of the complaint,” and that the agency’s interpretation of the statute as requiring only notification of the fact the investigation has been completed and any appropriate actions taken is reasonable and therefore entitled to deference.

### LEGAL ANALYSIS

Claims that challenge an agency’s construction of a statute it administers are ordinarily subject to the standard of review articulated in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). In Chevron, the Supreme Court mandated a two-step process for reviewing an agency’s construction of the statute it administers. First, a court considers whether Congress spoke directly to the question at issue: if so, “that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” Id. at 842-43. If, however, the statute is unclear, “the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” Id. at 843. In answering that question, “considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer.” Id. at 844. The rationale for this deference is that the agency’s decision as to the meaning of the statute involves

“reconciling conflicting policies and a full understanding of the force of the statutory policy . . . [and] depend[s] upon more than ordinary knowledge respecting the matters subjected to agency regulations.” Id. In short, “a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.” Id.

Both parties claim that the statute is clear in its intent. “[W]hen a statute is clear and unambiguous, consideration of administrative interpretation contrary to such language is inappropriate; the agency cannot by its interpretation, override the congressional will as memorialized in the statutory language.” Mylan Pharm., Inc. v. Henney, 94 F. Supp. 2d 36, 47 (D.D.C. 2000) (internal quotations omitted). “Under the first step of Chevron, the reviewing court must first exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue.” Bell Atlantic Telephone v. FCC, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (internal quotations omitted).

“The first traditional tool of statutory construction focuses on the language of the statute.”

Id. The provision at issue provides:

The organization shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under subchapter XVIII of this chapter) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such subchapter (or a person acting on the individual’s behalf). The organization shall inform the individual (or representative) of the organization’s final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.

42 U.S.C. § 1320c-3(a)(14) (emphasis added). The term “final disposition” is not defined in the statute, nor is there any additional discussion of this term. Plaintiff notes that “final disposition” is defined as “final determination.” See Pl. Mot. at 10; see also Black’s Law Dictionary 484 (7<sup>th</sup>

ed. 1999) (“a final settlement or determination <the court’s determination of the case>.”).

Plaintiff argues that the term indicates that the substantive result must be provided, and therefore, a beneficiary complainant must be informed if there were quality of care issues identified with respect to a particular practitioner. Defendants contend that the term “disposition” is defined as “the act of disposing,” Def. Cross Mot. at 21, and therefore, what Congress intended was that a PRO should inform a beneficiary complainant of the fact that the complaint has been disposed of (i.e., merely procedural information), and should not provide the substance of the disposition.

While the term “final disposition,” standing alone, could arguably be interpreted as having either a procedural and substantive meaning, an examination of “the history, structure, and underlying policy purpose of the statute,” Bell Atlantic, 131 F.3d at 1048, supports the finding that § 1320c-3(a)(14) requires a PRO to inform beneficiary complainants of the substantive disposition of the complaint. Congress specifically considered and rejected language that would have required a PRO merely to inform a complainant that his complaint had been received and addressed. As noted in the conference report, the House bill, which was titled “Improve peer review responsiveness to beneficiary complaints” provided that:

(i) PRO’s [were required] to conduct appropriate reviews of all written complaints by beneficiaries about the quality of services not meeting professionally recognized standards. The PRO is required to inform the beneficiary of its conclusions and final disposition.

(ii) Before the PRO concludes that the quality of care is substandard, it must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.

H.R. Conf. Rep. 99-1012 at 358 (Oct. 17, 1986) (emphasis added). The Senate Bill, on the other hand, did not provide for a PRO to disclose whether the standard of care had been met, but required only that “[t]he PRO is required to inform the individual that the organization has received the complaint and will take appropriate action.” Id. at 360. The conference report states

that “[t]he conference agreement includes the Senate amendment with the following modifications.” Id. at 361. The first modification is that “[i]f the PRO makes a final determination with respect to whether the services which are the subject of a complaint did or did not meet professionally recognized standards of care, the PRO would be required to inform the beneficiary involved (or the beneficiary’s representative) of any final action taken.” Id. (emphasis added). In addition, “[b]efore the PRO concludes that the services involved did not meet professionally recognized standards of care, the PRO would be required to provide the practitioner (or other person concerned) with reasonable notice and opportunity for discussion.” Id.

While the language as enacted is “final disposition,” and not, as suggested in the conference report, “final action taken,” this change cannot be interpreted to mean that procedural, rather than substantive, information is all that the PRO should provide. The Senate bill unambiguously provided only for the disclosure of procedural information – that the complaint had been received and that the PRO would take appropriate action. This was expressly rejected by the conference agreement in favor of the provision of information regarding the PRO’s final action. Defendants’ interpretation would suggest that the provision that the beneficiary be informed “of the final disposition” means that the Senate version basically prevailed except that the PRO must notify the beneficiary complainant that the investigation had been completed. The Court cannot read the requirement that the beneficiary be informed of the final disposition of the complaint to mean simply that Congress rejected a provision which would have required notice that the complaint had been received in favor of a provision that would have required notice that an investigation had been completed. Such a reading is illogical as well as inconsistent with the conference agreement’s rejection of the Senate bill as written, and with the conference report

statement that the provision agreed to would require the PRO to notify the beneficiary complainant of the final action taken.

Similarly, the Court cannot agree with defendants' argument that the change from the House bill's language requiring notification of "conclusions and final determinations," to the statute's language requiring notification of the "final disposition," means that a beneficiary complainant is to receive no substantive information. Such an interpretation is inconsistent with the remainder of the section, which discusses a PRO's use of a substantive determination by providing that: "Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion." 42 U.S.C. § 1320c-3(a)(14). This sentence refers to the substantive disposition of a complaint, it does not provide for notice and discussion "before the PRO has disposed of the complaint," referring to a procedural disposition. Moreover, the provision was intended to "improve peer review responsiveness to beneficiary complaints." H.R. Conf. Rep. 99-1012 at 361. The first sentence of the provision provides that PROs are required to investigate such complaints. Defendants read the second sentence to require that PROs do no more than inform beneficiaries that they have performed the duties required in the first sentence. This does little, if anything, to improve responsiveness to beneficiary complaints. But more importantly, defendants' interpretation would render Congress' intent in providing that a Medicare consumer be informed of the "final disposition" of the investigation a nullity, since the beneficiary will learn nothing from the form of the notice advocated by defendants.

The interpretation now advanced by defendants in this litigation as "clear" is also seriously clouded by the fact that in proposing rules after the 1986 amendment which added

§ 1320c-3(a)(14), defendants did not interpret the statute to require the minimal, procedural information they argue Congress unambiguously intended.<sup>5</sup> After the 1986 amendment, HCFA proposed a new regulation entitled “Review of beneficiary complaints.” The rule provided:

In accordance with section 1154(a)(14) [§ 1320c-3(a)(14)] of the Act, for beneficiary complaints about the quality of services, the PRO must conduct a review of the complaint . . . and--

(a) At least 30 days prior to notification of the beneficiary concerning disposition of the complaint, provide the practitioner or individual concerned with the complaint an opportunity for discussion before making a determination that the quality of services does not meet professionally recognized standards of health care; and

(b) In accordance with . . . this chapter, inform the beneficiary or the beneficiary’s representative whether the quality of care meets professionally recognized standards of health care, and, if not, the corrective action to be taken.

54 Fed. Reg. 1956, 1964 (1989) (emphasis added). HCFA explained that

Section 1154(a)(14) of the Act [§ 1320c-3(a)(14)], as added by section 9353(c) of Pub. L. 99-509, requires PROs to conduct an appropriate review of all written complaints from beneficiaries or their representatives about the quality of services . . . not meeting professionally recognized standards of health care. . . . We would require that, in conducting an appropriate review of a beneficiary’s complaint, the PRO . . . [i]nform the beneficiary or the beneficiary’s representatives whether or not the quality of care meets professionally recognized standards of health care, and the corrective action to be taken if necessary (that is denial of payment, education, intensified review, or sanctions) . . . We note that the nature of the complaint may be so unique or the service in question so specific that implicit identification of an individual physician concerned could be an unavoidable consequence of compliance with section 1154(a)(14) of the Act. We considered precluding PROs from providing any information to the beneficiary that might identify the concerned physician or practitioner. However, we believe that section 1154(a)(14) of the Act requires that the information discussed above be provided to the beneficiary, which, in some cases, may have that unintended effect. We are proposing to amend §§ 466.70 and 466.106 and the PRO confidentiality regulations at § 476.133 to set forth these requirements.

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<sup>5</sup> While the agency is not bound by the interpretation it advanced in proposing these rules, which have not yet become final, its interpretation both supports plaintiff’s reading of the statute and undercuts defendants’ argument that an opposite interpretation is clear from the plain language of the statute.

Id. at 1960 (emphasis added).<sup>6</sup> Defendants thus proposed amending the regulation governing disclosure of information about practitioners, reviewers, and institutions to provide an exception to the prohibition against disclosure of practitioner-identifying information by which a “PRO, in response to a beneficiary complaint . . . that is so unique or the service in question so specific, may identify the individual practitioner or other practitioner, without their consent, as an unavoidable consequence of responding to the complaint.” 54 Fed. Reg. at 1964.

It is clear from this proposal that HCFA understood the proposed regulations as necessary to bring the regulatory scheme into compliance with the statutory amendments, not as a discretionary change in policy.

Again, in November 2000, HCFA noted its intention to propose a rule to comply with § 1320c-3(a)(14):

This rule would change our policy regarding the disclosure of peer review organization (PRO) information in responding to beneficiary complaints about physicians, other practitioners, and other institutional and non-institutional providers of health care, including Health Maintenance Organizations and Competitive Medical Plans. Under the proposal, we would permit the disclosure of PRO information about physicians and other individual practitioners without their permission to the extent necessary to comply with section 1154(a)(14) of the Social Security Act. This section requires PROs to conduct reviews of beneficiary complaints about the quality of services that do not meet professionally recognized standards of health care and inform each beneficiary of the final disposition of his or her complaint.

65 Fed. Reg. 73838, 73844 (2000) (emphasis added).

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<sup>6</sup> The proposed rulemaking also provided a model form letter response to a beneficiary complainant to be used when the quality of care is found to have failed to meet professionally recognized standards of health care. The letter would inform the beneficiary: “We have reviewed your case and have found that the quality of services you received does not meet professionally recognized standards of health care. We have taken the following steps to correct this situation: (list specific corrective actions taken--education, intensified review, sanctions).” 54 Fed. Reg. at 1967.

Moreover, a review of the context and structure of the Peer Review Act further supports plaintiff's interpretation. "In determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme." FDA v. Brown & Williamson, 529 U.S. 120, 121 (2000). Defendants argue that the distinction between "final disposition" and the various terms used by Congress elsewhere in the statute when it directed PRO's to disclose "highly sensitive" substantive information demonstrates that Congress did not intend such disclosures here. Def. Cross Mot. at 24 (citing Rusello v. United States, 464 U.S. 16, 23 (1983) ("where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion")). Defendants cite § 1320c-3(a)(9)(B) as an example. This section was enacted four years after § 1320c-3(a)(14), and it provides that if a PRO finds that a physician has provided services that are not cost effective, not medically necessary, or do not meet professionally recognized standards of care, and determines a corrective plan should be entered into, the PRO shall notify the State boards responsible for the licensing or disciplining of the physician "of its finding and any action taken as a result of the finding." 42 U.S.C. § 1320c-3(a)(9)(B) (West Supp. 2000). However, the statute makes clear that Congress has used a variety of terms to provide for substantive disclosures in the statute. See also 42 U.S.C. § 1320c-3(a)(3)(a) ("of such determination"); § 1320c-3(e)(3)(A) ("results of the review"). Even if Congress can be presumed to have intended that different amounts of information be provided, there is no basis to infer that while in the above-cited instances the various terms employed were intended to require the provision of substantive content, the term "final disposition" should be

limited to nothing more than a procedural fact.

Defendants also argue that “whenever Congress has allowed or mandated the disclosure of confidential, practitioner-specific information relating to quality of care reviews, it has done so by amending section 1320c-9(b).” Def. Rep. at 9. For example, defendants cite the 1990 amendment of § 1320c-3(a)(9)(B), which provided that if a PRO finds that a physician has provided services in violation of § 1320c-5,<sup>7</sup> the PRO is required to inform the appropriate State review board(s) “of its finding and of any action taken as a result of the finding.” Pub. L. 101-508, § 4205(d)(1)(A) (1990). Congress simultaneously amended § 1320c-9(b) to add a subsection providing that disclosure of information which may identify specific health care providers is permitted as necessary to provide such notice. Pub. L. 101-508, §§ 4205(d)(1)(B) (1990) (adding § 1320c-9(b)(1)(D)). Defendants argue that because Congress failed to amend § 1320c-9(b) when it enacted § 1320c-3(a)(14), it must be presumed that Congress did not intend to require that practitioner-identifying information be disclosed to beneficiary complainants, other than as permitted by regulations, *i.e.*, with the consent of the practitioner.

As an initial matter, it is not the case, as argued by defendants, that the statute is symmetrical and that “whenever Congress has allowed or mandated the disclosure of confidential, practitioner-specific information relating to quality of care reviews, it has done so by amending § 1320c-9(b).” Def. Rep. at 9. For instance, Congress amended § 1320c-3(a)(2) in 1987 to provide that a PRO could deny payment under Medicare for services that were determined not to meet professionally recognized standards of care. See Pub L. 99-272, §

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<sup>7</sup> Section 1320c-5 provides that health care practitioners providing services under Medicare must assure such services are provided economically, are provided only when medically necessary, meet professionally recognized standards of care, and are supported by evidence of medical necessity and quality of care. 42 U.S.C. § 1320c-5(a)(1)-(3).

9403(a) (1987). Section 1320c-3(a)(3)(A) provides that whenever a PRO makes a determination that payment is not approved, the PRO “shall promptly notify such patient . . . of such determination.” In 1989, Congress amended § 1320c-3 to add subsection (a)(3)(E), which provides that if payment were denied for quality of care reasons, the notice to the patient should state that “[i]n the judgment of the peer review organization, the medical care received was not acceptable under the medicare program. The reasons for the denial have been discussed with your physician.” 42 U.S.C. § 1320c-3(a)(3)(E) (enacted by Pub L 101-239, § 6224(b) (1989)). This section, providing for disclosure to a beneficiary that the medical care provided by their physician was not acceptable, identifies practitioner-specific information and does not have a corresponding provision in § 1320c-9(b) permitting such disclosure.

While defendants cite one example where Congress did simultaneously amend § 1320c-3(a) and § 1320c-9(b), to provide separately for a disclosure function and express permission for disclosure, the other exceptions (contained in § 1320c-9(b)(1)(A)-(C)) to the prohibition against disclosing practitioner specific information do not have corresponding provisions in the “functions” section of the statute.<sup>8</sup> Moreover, there are other “functions” enumerated in § 1320c-3 that contain disclosure requirements that would identify practitioners and do not have separate, corresponding disclosure provisions in § 1320c-9(b). See 42 U.S.C. § 1320c-3(a)(3)(A), § 1320c-3(a)(16); § 1320c-3(e)(3). The Court finds that § 1320c-9(a)(1), which provides that a PRO may disclose information “to the extent that may be necessary to carry out the purposes of this part,” makes clear that § 1320c-9 recognizes that disclosure, including disclosure of

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<sup>8</sup> In addition, none of the disclosures specifically listed in § 1320c-9(d) relates to beneficiary disclosures. All of the permissible disclosures listed there are disclosures to governmental entities and agencies. In contrast, the disclosures to beneficiaries permitted and required by the statute are contained in § 1320c-3.

practitioner-identifying information, may be permitted or required by other provisions of the statute, including § 1320c-3. The fact that § 1320c-9(b)(1)(A)-(D) provides four bases for such disclosure, including one which is also enumerated in § 1320c-3, cannot be read to deprive § 1320c-9(a)(1) of its meaning.<sup>9</sup>

Defendants also argue that interpreting § 1320c-3(a)(14) as plaintiff suggests would nullify § 1320c-9(d), which was enacted four years after § 1320c-3(a)(14). This argument is not persuasive. Section 1320c-9(d) provides that no patient record, or “document or other information produced by [a PRO] . . . in connection with its deliberations in making determinations under section 1320c-3(a)(1)(B) or 1320c-5(a)(2) of this title shall be subject to subpoena or discovery in any administrative or civil proceeding.” Defendants argue that because Mr. Shipp, who is a plaintiff in a civil case against the practitioners investigated by the PRO, is seeking to obtain through § 1320c-3(a)(14) what Congress prohibited him from obtaining when it enacted § 1320c-9(d) four years later, plaintiff’s interpretation of § 1320c-3(a)(14) cannot be credited.

The provision, on its face, appears to apply only to determinations under those sections delineated, and not determinations of beneficiary complaints pursuant to § 1320c-3(a)(14). But even if one were to assume that the provision is intended to cover § 1320c-3(a)(14)

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<sup>9</sup> Similarly, the fact that § 1320c-9(a)(2) provides that the disclosure of confidential PRO information is permitted “in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care,” does not negate the fact that § 1320c-9(a)(1) provides for disclosure as necessary to carry out the purposes of the peer review statute. Congress did not delegate the determination of all permissible disclosures to the agency, it explicitly provided that the statute itself could require or permit disclosures without regard to the regulatory scheme. Moreover, the agency was not interpreting § 1320c-3(a)(14) when it promulgated its regulatory scheme in 1985 pursuant to § 1320c-9(a)(2), as it had not yet been enacted.

determinations as well, it is clear that Congress did not intend § 1320c-9(d) to prohibit the disclosure of all substantive information that the statute otherwise provides may be disclosed to beneficiaries. The prohibition on civil discovery contained in § 1320c-9(d) is significantly broader than the limited amount of substantive information provided for under § 1320c-3(a)(14). That Congress intended to make certain limited information available to a beneficiary complainant in response to a complaint, and provide that such information, as well as additional information, is not otherwise subject to subpoena, is the most reasonable interpretation, not that Congress never intended § 1320c-3(a)(14) to permit any substantive disclosure. This interpretation is supported by the fact that § 1320c-3 also provides that whenever a PRO makes a determination that payment for Medicare services is denied for quality of care reasons, the patient shall be notified of the denial and informed that “[i]n the judgment of the peer review organization, the medical care received was not acceptable under the medicare program. The reasons for the denial have been discussed with your physician.” 42 U.S.C. § 1320c-3(a)(3)(E). This provision was, like § 1320c-3(a)(14), enacted before § 1320c-9(d), and unambiguously provides for limited substantive disclosure to a Medicare beneficiary. Defendants argument that the subsequent enactment of § 1320c-9(d) makes clear Congress’ intent to withhold all information relating to quality of care determinations from beneficiaries is untenable in light of § 1320c-3(a)(3), which unambiguously provides for such a disclosure. Rather, Congress has provided for certain limited disclosures to beneficiaries regarding quality of care issues in both § 1320c-3(a)(3) and (a)(14), while prohibiting beneficiaries broader access to deliberative information though subpoena or civil discovery.<sup>10</sup>

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<sup>10</sup> Defendants’ reliance on Armstrong v. Dwyer, 155 F.3d 211 (3d Cir. 1998), is misplaced. The court in Armstrong interpreted the § 1320c-9(d) prohibition on the discovery of

Finally, defendants argue that the HCFA regulations promulgated in 1985 provided that practitioner-identifying information was not to be disclosed absent the consent of the practitioner, and that Congress was aware of, and left intact, that policy when it enacted § 1320c-3(a)(14) the following year. The argument that Congress did not alter, and therefore implicitly adopted, that policy is dependent on defendants' premise that § 1320a-3(a)(14) does not provide for a substantive disclosure, it does not demonstrate that defendants' interpretation is correct. As discussed above, the argument is undermined by the plain language of the statute and defendants' proposed regulations issued subsequent to the enactment of § 1320c-3(a)(14), which interpret that provision to alter the regulatory scheme that had been promulgated prior to its enactment.<sup>11</sup>

### CONCLUSION

For the reasons stated herein, plaintiff's motion for summary judgment is granted, and defendants' motion for summary judgment is denied. A separate order accompanies this opinion.

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ELLEN SEGAL HUVELLE

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PRO information and deliberations broadly in light of the HCFA regulatory definitions of "PRO information" and "PRO deliberations" to preclude the production of both the quality of care inquiries sent to the physician by the PRO and the physicians responses thereto. Even assuming that § 1320c-9(d) should be interpreted to prohibit disclosure of the information at issue here, it does not purport to govern all disclosures to beneficiaries, only those that are sought by subpoena or through discovery.

<sup>11</sup> Because the Court finds that the statute requires a PRO to inform a beneficiary complainant of the substantive disposition of their complaint, the Court need not address defendants' alternative argument that the statute is ambiguous and therefore their interpretation is entitled to deference under Chevron's second step.

United States District Judge

Date:

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

<b>PUBLIC CITIZEN, INC.,</b>	:	
	:	
<b>Plaintiff,</b>	:	
	:	
v.	:	<b>Civil Action No. 00-0731</b>
	:	<b>(ESH)</b>
<b>DEPARTMENT OF HEALTH AND, HUMAN SERVICES, <i>et al.</i>,</b>	:	
	:	
<b>Defendants.</b>	:	

**ORDER**

\_\_\_\_\_ Upon consideration of the Cross-Motions for Summary Judgment, it is hereby **ORDERED** that plaintiff's Motion for Summary Judgment [40-1] is hereby **GRANTED**. It is

**FURTHER ORDERED** that defendants' Motion for Summary Judgment [41-1] is **DENIED**. It is

**FURTHER ORDERED** that HCFA's regulations prohibiting disclosure of the results of PRO investigations under 42 U.S.C. § 1320c-3(a)(14) are invalid because they are contrary to law. It is

**FURTHER ORDERED** that the provisions in HCFA's PRO Manual prohibiting disclosure of the results of § 1320c-3(a)(14) investigations are contrary to law. It is

**FURTHER ORDERED** that within 20 days of the date of this Order, defendants will send a letter to PROs informing them that PROs are required to disclose the results of PRO investigations to beneficiary complainants pursuant to § 1320c-3(a)(14).

**SO ORDERED.**

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ELLEN SEGAL HUVELLE  
United States District Judge

Date: