UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA <u>ex rel.</u> MATTHEW I. GELFAND, M.D. and STATE OF NEW YORK <u>ex rel.</u> MATTHEW I. GELFAND, M.D.,

Plaintiffs,

<u>MEMORANDUM</u> OPINION AND ORDER

-against-

CV 02-6079 (LDW)(ETB)

SPECIAL CARE HOSPITAL MANAGEMENT CORP., et al.,

Defendants.

-----X UNITED STATES OF AMERICA, and STATE

OF NEW YORK, <u>ex rel.</u> ENRICO MONTAPERTO,

Plaintiffs,

-against-

CV 05-4911 (LDW) (ETB)

NEW PARKWAY HOSPITAL, et al.,

Defendants.

Before the court are cross-motions for a protective order governing discovery in these two related actions. The first motion is brought by all defendants, who propose one form of a protective order. Although the State of New York does not object to the defendants' proposed version, it has submitted a cross-motion containing its own proposed alternative order. The crucial difference between the two proposed versions appears to be the redaction of patient identifying information. For the following reasons, the defendants' motion is denied and the

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State of New York's motion is granted in part and denied in part.

### Facts

Familiarity with the facts of the underlying actions is presumed. The within actions are <u>qui tam</u> actions, alleging that the defendants filed more than 27,000 false claims for Medicare and/or Medicaid reimbursement for substance abuse services rendered to patients over a period of approximately five years. The cases are brought by two different relators and are being jointly pursued by two intervening plaintiffs, the United States (the "Government") and the State of New York (the "State"), under the federal False Claims Act and the New York State False Claims Act.

By an undated letter motion that was received by the Court on April 12, 2010, defendants New York Downtown Hospital and Long Beach Medical Center, on behalf of all defendants, submitted a proposed protective order that they seek to have approved by the Court. Defendants' protective order proposes that all patients who were treated at the defendant facilities for substance abuse during the time in question be provided notice that their patient records may be disclosed during the course of these litigations and that such patients be provided with an opportunity to "opt out" of having their records disclosed. (Def. Mot. for Protective Order 3.) Defendants' proposed order does not provide for the redaction of patient identifying information or of any "confidential communications" contained in the substance abuse records.<sup>1</sup> According to defendants, redacting such information would be extremely costly, would result in undue delay and would deprive them of information central to their defense. (Def. Mot. for Protective Order

<sup>&</sup>lt;sup>1</sup> "Confidential communications" are communications made by a patient to a program in the course of diagnosis, treatment or referral for treatment. <u>See</u> 42 C.F.R. § 2.63.

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By letter dated April 12, 2010, the State submitted an alternative proposed protective order, which "contains the same protections as defendants' proposed Order governing the disclosure of trade secrets, medical records not reflecting substance abuse treatment, HIV information and substance abuse records." (New York State's Mot. for Protective Order 1.) However, the State's proposed order seeks to further restrict the disclosure and use of patient substance abuse records by redacting patient identifying information. The State's proposed order "limits disclosure of the patients' substance abuse records, including the Confidential Communications therein . . . to a form from which all patient identifying information is redacted." (New York State's Mot. for Protective Order 5.) The State also proposes that random sampling be used to significantly limit the cost and burden of the discovery sought herein and that notice and an opportunity to object be provided to patients prior to any disclosure of their records. (New York State's Mot. for Protective Order 6.)

By letter dated May 10, 2010, the Government responded to the two protective orders proposed by defendants and the State. In its response, the Government states that it opposes the defendants' proposed protective order and endorses the State's proposed order. However, the Government requests that a further protection be added to the State's proposed order providing for the creation of a "filter team" by each party, which would be responsible for redacting the patient identifying information from the substance abuse records prior to disclosure. (United States Letter Response 1.) Defendants object to the Government's request for a "filter team."

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#### DISCUSSION

"Federal law restricts the disclosure of information obtained 'in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research' conducted by the United States or with federal money." United States ex rel. Chandler v. Cook County, 277 F.3d 969, 982 (7th Cir. 2002) (quoting 42 U.S.C. § 290dd-2). The purpose of such restrictions is "to protect 'the patient, the physician-patient relationship, and the treatment programs." U.S. ex rel. Chandler, 277 F.3d at 981 (quoting 42 C.F.R. § 2.64(d)). "It is not only the privacy rights of individual patients that are at stake here, but also the continued effectiveness and viability of important substance abuse treatment programs." U.S. ex rel. Chandler, 277 F.3d at 981 (citing United States v. Smith, 789 F.2d 196, 205-06 (3d Cir. 1986)); see also Whyte v. Connecticut Mut. Life Ins. Co., 818 F.2d 1005, 1010 (1<sup>st</sup> Cir. 1987) ("[A]bsolute confidentiality is an indispensable prerequisite to successful [substance abuse] research . . . [and] treatment."). "Without guarantees of confidentiality, many individuals with [substance abuse] problems would be reluctant to participate fully in [substance abuse] programs." Whyte, 818 F.2d at 1010; see also U.S. ex rel. Chandler, 277 F.3d at 981 ("Patients will be less willing to seek treatment if patient confidentiality is not strictly protected.").

Information contained in substance abuse records is divided into two categories -"confidential and non-confidential communications." <u>U.S. ex rel. Chandler</u>, 277 F.3d at 982. With respect to confidential communications, some of which are contained in the substance abuse records at issue herein, in the absence of patient consent, such information may be disclosed by court order "only if": (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury . . . (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or (3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of confidential communications.

<u>Id.</u> at 983 (quoting 42 C.F.R. § 2.63(a)). The parties do not dispute that none of the foregoing exceptions are applicable to the within actions. However, all parties seek to have the nonparty patients' confidential communications disclosed, whether patient identifying information is redacted, as the State proposes, or left unredacted, as defendants propose. All parties seem to assert that disclosure of confidential communications is permissible where patient identifying information, whether it be statute, regulation or case law.

Contrary to statements made by the Court at oral argument, additional research conducted by the Court appears to yield a different conclusion. As discussed above, there are only three exceptions by which confidential communications may be disclosed, absent patient consent, none of which apply to the within action. "Absent one of the enumerated exceptions, a court may not order disclosure of a patients' confidential communications, even if the party seeking the communications establishes good cause and needs to use the protected records to prove its case." <u>United States ex rel. Chandler v. Hektoen Inst. for Med. Research</u>, No. 97 C 514, 2003 U.S. Dist. LEXIS 17569, at \*13 (N.D. Ill. Oct. 1, 2003); <u>see also Whyte</u>, 818 F.2d at 1010 (denying disclosure of confidential communications where none of the exceptions set forth in 42 C.F.R. § 2.63 applied and rejecting defendant's argument that it needed access to the records to defend its

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position in the litigation). "[T]he regulations place the need for confidentiality to assure successful [substance abuse] treatment above a party's evidentiary needs, even if that information is of vital importance to the party." <u>U.S. ex rel. Chandler</u>, 2003 U.S. Dist. LEXIS 17569, at \*14 (citing <u>Whyte</u>, 818 F.2d at 1010).

Moreover, at least one court has explicitly rejected the position asserted by the parties herein that confidential communications may be disclosed where patient identifying information has been redacted. In <u>United States ex rel. Chandler</u>, defendant Cook County argued that if patient identifying information were redacted from the substance abuse records, "then a disclosure (as defined by the regulations) has not been made and the regulations do not apply to the records." <u>United States ex rel. Chandler</u>, 2003 U.S. Dist. LEXIS 17569, at \*18. In rejecting this argument, the court held:

This argument goes against the language and spirit of the statute and regulations. First, the absurd result of this argument would be that as long as the patient's name, address and social security number were removed, the entire remainder of the patient file (including confidential communications which would likely contain anecdotal material from which a patient's identity may be inferred) would be open to public perusal. This goes against the intent of the statute and regulations which is to afford heightened protection to drug and alcohol records. It also goes against the language of the statute. The "information" referred to in § 2.11 includes all confidential patient information, including confidential communications, the court must determine at the threshold that one of the subsections of § 2.63(a) applies <u>or a party cannot have access to the confidential</u> communications.

Id. at \*18-19 (citing In re August, 1993 Regular Grand Jury, 854 F. Supp. 1380, 1384 (S.D. Ind.

1994) and Mahoney v. Vill. of Fox Lake, No. 90 C 1415, 1990 WL 251808, at \*3 (N.D. Ill. Dec.

27, 1990)) (emphasis added). According to the court in United States ex rel. Chandler, and in

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direct contrast to what the parties herein propose, "[t]he regulations do not allow the disclosure of confidential communications if the patients' identities have been removed, they only allow the disclosure if one of the subsections of § 2.63(a) applies and if good cause is demonstrated . . . ." <u>Id.</u> at \*19. Since it is undisputed that none of the enumerated exceptions is applicable to the within actions, "any confidential communications must be redacted" prior to disclosure. <u>U.S. ex</u> <u>rel. Chandler</u>, 277 F.3d at 983.

Accordingly, the Court endorses the State's proposed protective order to the extent that it provides for the redaction of patient identifying information and commends the State for its diligence in the formulation and presentation of its position to protect the identities of those participating in the substance abuse programs that are the subject of this action. The Court further endorses the State's position that random sampling shall be utilized in order to reduce the otherwise heavy burden of redaction and production which rests primarily with the defendant institutions and facilities. However, the Court imposes a further restriction on the disclosure of the substance abuse records at issue herein such that, unless patient consent is received during the notice period, as discussed below, all confidential communications must be redacted prior to disclosure. "To hold otherwise would violate the regulations' clear heightened protection of confidential communications and would contravene Congress' clear intention to encourage substance abusers to seek treatment freely and without fear of exposure or prosecution." <u>U.S. ex</u> rel. Chandler, 2003 U.S. Dist. LEXIS 17569, at \*26.

In addition, whether disclosing confidential or non-confidential communications, the regulations require that the patients whose information will be disclosed be provided with "[a]dequate notice in a manner which will not disclose patient identifying information to other

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persons" as well as "[a]n opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order [authorizing disclosure]." 42 C.F.R. § 2.64(b)(1-2); see also Granger v. McBride, No. 2:04 CV 8, 2006 U.S. Dist. LEXIS 34689, at \*14 (N.D. Ind. May 24, 2006). Such notice "must be provided to the nonparties prior to the disclosure of any information contained in their patient files," as the State proposes. Granger, 2006 U.S. Dist. LEXIS 34689, at \*18 (citation omitted); see also U.S. ex rel. Chandler, 277 F.3d at 983 ("The statute and regulations do not contemplate even limited disclosure ... without notice."). Accordingly, to the extent it has not already done so, the State is directed to ensure that its proposed form of notice is consistent with the requirements of 42 C.F.R. §§ 2.31 and 2.64. The defendants shall serve the notice on all nonparty patients whose records may be disclosed during the course of discovery herein and provide them thirty (30) days to respond in writing. See Granger, 2006 U.S. Dist. LEXIS 34689, at \*18 (allowing for thirty-day response period). The Court will take up any objections to disclosure upon the expiration of the thirty-day time period for responses. With respect to those patients who consent to disclosure, or who fail to respond entirely, all non-confidential communications - and, where consent is obtained, confidential communications - may be disclosed upon the expiration of the thirty-day time period for responses, with all patient identifying information redacted.

As to the Government's request for a "filter team" to oversee redaction, the Court denies this application. This would be another level of oversight and no reasons are evident why each party cannot be responsible for its own redaction responsibilities. To require the presence of team members, presumably made up of representatives of all parties herein, would greatly

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increase the already burdensome chores ahead with respect to document production.

Lastly, the parties are directed to use their good faith efforts to agree upon a protocol for the production of a random sampling of documents to ensure that all of the issues involved in this action are fairly determined on the merits while also minimizing the otherwise heavy burden that falls on defendants. In the event that the parties are unable to agree on a joint protocol, any party's protocol shall be submitted to the Court no later than June 30, 2010.

### **CONCLUSION**

For the foregoing reasons, the State of New York's motion for a protective order is granted in part and denied in part, such that the Court imposes the further restriction that, absent patient consent, confidential communications must be redacted from the nonparty patient records prior to any disclosure. Notice and an opportunity to respond is to be provided to the nonparty patients prior to any disclosure. The defendants' motion for a protective order is denied. The State is directed to file a revised protective order within five (5) days of the date of this Order.

#### SO ORDERED:

Dated: Central Islip, New York June 10, 2010

> /s/ E. Thomas Boyle E. THOMAS BOYLE United States Magistrate Judge