



State of South Carolina *Department of Mental Health*

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January 6, 2016

Meredith Williams, Senior Counsel
Industry Guidance Branch
U. S. Department of Health and Human Services
Office of Inspector General
Office of Counsel to the Inspector General
Room 5527, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: South Carolina Department of Mental Health
Advisory Opinion Request No. R 1046

Dear Ms. Williams:

This is to supplement my response to your request for additional information regarding a public procurement contract for Qualified Providers associated with pharmacy companies to assist South Carolina Department of Mental Health (SCDMH) Mental Health Center outpatients, who qualify for Pharmaceutical Assistance Programs offered by various pharmaceutical companies, for those patients to obtain free medications prescribed by their Mental Health Center physician ("Arrangement" as enclosed in my original request for an Advisory Opinion).

Based upon a favorable advisory opinion SCDMH will continue, and if needed, amend the contract/Arrangement, consistent with the OIG Advisory Opinion.

I understand that the Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See Section 1128B(b) of the Act, where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback"

MISSION STATEMENT

To support the recovery of people with mental illnesses.



transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an Advisory Opinion is being submitted to the Department of Health & Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an Advisory Opinion is sought, to the best of my knowledge and belief.

The Arrangement (attached to my initial request for an opinion) is the current SCDMH public procurement contract for contract Qualified Providers to provide this Medication and Patient Assistance Program (PAP) services to SCDMH outpatients. This contract covers 17 SCDMH Mental Health Centers (MHC) across South Carolina, and includes more than 50 individual office locations which may currently select one of four contract Qualified Providers (QP).

SUPPLEMENTAL BACKGROUND INFORMATION

As additional background, late last summer SCDMH received complaints from a pharmacy provider who is not a contract QP under the Arrangement, alleging that in some MHCs, the local QP and/or MHC staff were not following the Arrangement. This non-contract pharmacy also alleged that the contract/Arrangement may itself be in violation of the Act.

Specifically, the complaints alleged:

- 1.** Providing automatic refills (a subsequent contract Change Order, included in my request, removed this clause from the written contract)
- 2.** Posting, displaying, distributing or providing marketing or other materials at the MHC which state or imply that the QP provides a pharmacy or pharmacy related services at the MHC onsite location.
- 3.** Not referring and/or not providing PAP assistance services only to MHC patients who are eligible for PAP services, which may result in the patient receiving free medication from the respective PAP, and/or the patient choosing the QP to fill their MHC and other prescriptions by QP mail order.
- 4.** Not informing MHC referred patients that they have Freedom of Choice as to which pharmacy (local or QP mail order) fills their prescriptions, prescribed by MHC physician and/or other medical provider.

Upon receiving these allegations, SCDMH contacted the MHCs named by the non-contract pharmacy as to that pharmacy's allegations. SCDMH received written assurance from those MHC Contract Monitors, that while in the past in some MHCs named by the non-contract pharmacy, there may have been confusion or conflict with the written contract, that the local

QP was currently complying with the written contract, e.g. no sign or reference to the QP operation as a "Pharmacy", patients referred for PAP services were not told that the onsite QP was their sole source for medications, etc.

In early September, 2015, a representative from SCDMH Community Mental Health and I visited the MHCs identified by the non-contract pharmacy. At the time of our visits to individual locations covering eight offices and six counties, we could not substantiate a current conflict with the contract/Arrangement. Although not specifically required by the contract, one location had not posted the Freedom of Choice notices (see my prior response). Before we left that location, the Freedom of Choice notices were posted.

Since late summer, SCDMH has continued to review and monitor performance of the contract/Arrangement with SCDMH Medical Affairs, Corporate Compliance, Pharmacy Outlet Consultants, applicable MHC Directors and MHC Contract Monitors.

During that time, when SCDMH has received specific reports of contract non-compliance, we have investigated, and as needed, notified the respective QP and MHC Contract Monitor for corrective action or other compliance. By a recent statewide survey, SCDMH has received written assurance from all MHC Contract Monitors, and from each of the four QPs, that the local QP is fully complying with the contract/Arrangement.

SUPPLEMENTAL INFORMATION TO MY REPLY

To supplement my response to your question asking if the MHC identifies which patients may enroll in a PAP:

When a MHC patient is prescribed a medication by their MHC physician and the patient (including a Medicaid/Medicare patient) tells MHC staff, or the MHC otherwise believes, that the patient is unable to pay for their medication, the patient is referred to the onsite contract QP for PAP assistance. At that time, it may be difficult to know if a patient is, or is not, eligible for free medication through various pharmaceutical company PAPs. While PAPs are similar, each has its own specific eligibility criteria, policy, and procedure.

Some pharmaceutical company PAPs do limit eligibility if a patient has any prescription drug insurance coverage. Other pharmaceutical company PAPs do not have an absolute exclusion, and will consider PAP eligibility for a low income patient (uninsured or insured) who is unable to pay for the needed medication if:

- a. The patient has been denied coverage for the prescribed medication and has a denial letter from the insurer, including Medicaid or Medicare Part D.
- b. The patient has exceeded the maximum prescriptions allowed by the insurer.

- c. The patient has reached the "doughnut hole" where patients have to pay out of pocket until they have reached a certain amount.
- d. The patient is denied, but still unable to afford the needed medication, and the denial is appealed as provided for by the PAP.

To supplement my response to your question asking if any MHC purchases its medications from the QP to administer to its patients:

Recently at one MHC, a box of PAP provided free medications was lost. While this was being investigated, the local MHC still needed those medications for patients scheduled that week and the order from Cardinal Health (the public procurement provider of medications for the MHC http://www.mmo.sc.gov/webfiles/MMO_spo/Contracts/rx-minn.pdf) would not arrive in time. In this instance, the MHC ordered specific medications from the local QP, and paid the QP the Cardinal Health rate, to tide them over until the Cardinal Health shipment arrived.

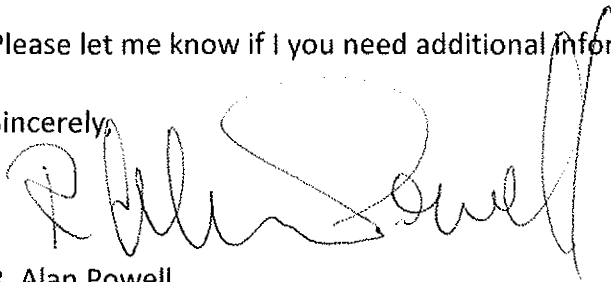
To supplement my response to "Who bills for the drugs and how Federal health care programs may reimburse the pharmacy or center for these drugs?":

As noted above, some MHC patients referred by MHC staff to the onsite QP for PAP assistance may have insurance (including Medicaid/Medicare), but all are low income, and the MHC believes that the patient cannot afford the MHC prescribed medication.

If a patient also chooses the QP to fill his/her other prescriptions by mail order, that may be billable to applicable third party payers including Medicaid/Medicare. If the patient does not choose the onsite QP, the QP and/or MHC may otherwise assist the patient in sending prescriptions to the patient's pharmacy of choice (e.g. Walgreens, CVS, Walmart, local pharmacy, etc.) and third party payers including Medicaid/Medicare may be billed.

Please let me know if you need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Alan Powell", written over a faint circular stamp.

R. Alan Powell
SCDMH General Counsel