



New York State Office of Medicaid Inspector General

Compliance Guidance

2014 – 01



Element #6 System for Routine Identification of Risk Areas

May 6, 2014

New York State Social Services Law Section 363-d (“§ 363-d”) and 18 NYCRR Part 521 (“Part 521”) establish required compliance program standards that certain healthcare providers must meet. The New York State Legislature found that requiring Medicaid providers to have compliance programs that meet these requirements is an effective way to control fraud, waste and abuse in the Medicaid program. The New York State Office of the Medicaid Inspector General’s (“OMIG’s”) Bureau of Compliance (“BOC”) conducts Compliance Program Reviews (“Reviews”) of Medicaid Providers¹ to assess if Providers are meeting all mandatory compliance program requirements.

PURPOSE OF THIS COMPLIANCE GUIDANCE

§ 363-d and Part 521 provide that OMIG will issue compliance program guidance on its website for those providing care, services or supplies under New York’s Medicaid program.² This *Compliance Guidance* is published to provide direction on how those subject to New York State’s mandatory compliance program obligations can meet the requirements of § 363-d(2)(f) and § 521.3(c)(6)

¹ The use of the word “Provider” herein shall be used to refer to any natural person or entity who is subject to New York State’s mandatory compliance program obligations in § 363-d and Part 521.

² N.Y. Soc. Serv. Law § 363-d(2), 18 NYCRR 521.3(b)

(hereinafter referred to as “Element #6”), as described in this *Compliance Guidance*. It also provides guidance as to what is expected when BOC conducts Reviews and assessments of Element #6 of Providers’ compliance programs.

BACKGROUND FOR ELEMENT #6 – SYSTEM FOR ROUTINE IDENTIFICATION OF RISK AREAS

Element #6 requires those who are subject to New York State’s mandatory compliance program requirements to adopt and implement:

[A] system for routine identification of compliance risk areas specific to the provider type, for self-evaluation of such risk areas, including but not limited to internal audits and as appropriate external audits, and for evaluation of potential or actual non-compliance as a result of such self-evaluations and audits, credentialing of providers and persons associated with providers, mandatory reporting, governance, and quality of care of [Medicaid] beneficiaries.³

§ 363-d and Part 521 require compliance programs to not only be appropriate to the type of service(s) being provided to Medicaid beneficiaries, but also to the Provider’s other characteristics (i.e. size, complexity, resources, and culture).⁴ Due to the diverse nature of Medicaid Providers throughout New York State, there is no one-size-fits-all approach to creating a compliance program that satisfies all Element #6 requirements.

DISCUSSION

A. Element #6 requires Providers to adopt and implement a system to routinely identify compliance risk areas. Adoption and implementation should also be read as requiring the system to be continuously operating. When conducting Reviews, BOC requires that, in order to comply with Element #6, the Provider offer evidence of the existence and operation of the system. The evidence⁵ can include, but is not limited to:

1. Evidence a system exists:

³ 18 NYCRR § 521.3(c)(6)

⁴ N.Y. Soc. Serv. Law § 363-d(1), 18 NYCRR 521.4

⁵ The best evidence is something in writing that is supported by statements by the Provider’s staff that what is documented as existing (the written evidence) is in fact operating. If the best evidence is not available during a Review, other evidence will be considered by BOC which includes proof of system outputs and the Provider’s activity based upon the results of an operating system.

- a. Description of the system being used. This may be in the form of policies and procedures, manuals, checklists, audit schedules, compliance or audit work plans, or memoranda.
- b. Description of how the system operates. This includes descriptions of the frequency of risk assessments, how the system identifies and stratifies its risk areas, how the system performs its work, what happens with outputs from the system⁶, and who receives the results of the system's output.
- c. Job descriptions or duties assignments. This includes those who are charged with operating the system and reporting on the results of the operation of the system.

2. Evidence a system operates:

- a. Reports on the output from the system. This may include written memoranda, reports, minutes, plans of correction, root cause analysis results or other documentation used to communicate the results of the operation of the system.
- b. Action taken in response to system outputs. This may include self-disclosures, refunds, adjustments or other billing or payment adjustments, changes in policies and procedures, root cause analysis activity, action taken by management or the governing board linked to system output reports.
- c. Changes or refinements made to the system for routine identification of compliance risk areas.

B. Element #6 requires a system for routine identification of compliance risk areas, specific to the type of services a Provider may offer under the Medicaid program. New York's Medicaid program includes many different provider types with different rules and reimbursement methods. Element #6 expects the system to be relevant to the specific Provider's services and characteristics. To assist Providers in identification of compliance risk areas, OMIG will publish a series of *Compliance Guidance* documents addressing risk areas by provider type throughout 2014. The current list of Compliance Risk Areas can be found in the BOC's Compliance Library on OMIG's website.

⁶ "Outputs from the system" or "system outputs" should be read to mean the results of the operation of the system being used.

- C. Element #6 requires that the system include self-evaluation of the risk areas. The self-evaluation can be accomplished by conducting internal audits and, when warranted, external audits to evaluate potential or actual non-compliance with Medicaid requirements. It is recommended that the process of self-evaluation include prioritizing risk areas, such that areas of highest risk⁷ will be assessed more frequently. When conducting Reviews, BOC will look for evidence of a compliance work plan, audit plans and other strategic or operational planning documents or reports to confirm that self-evaluations occur on a regularly scheduled basis. It should be noted that prioritization of risk areas by Providers within the same provider type may be quite different based upon differences in the Providers' size, complexity, resources, and culture.
- D. In addition to risks specific to the Provider's type referenced in Paragraph B, above, § 521.3(a) requires compliance programs to be applicable to billings, payments, medical necessity and quality of care, governance, mandatory reporting⁸, credentialing, and other risk areas that are or should with due diligence be identified by the Provider. During Reviews, BOC will look for evidence of compliance program connections to the Provider's oversight of each of these areas. This does not mean that the compliance function (or the compliance officer) must personally manage or oversee the control structures the Provider uses for oversight of these areas. Evidence of these connections could include:
1. reports on each area to the compliance officer that audits are being conducted;
 2. appropriately addressing deviations from acceptable standards in each area;
 3. issuance of reports from the compliance officer to the Provider's management or governing body on the results of audits;
 4. adopting or changing policies and procedures to address oversight of each area;
 5. adopting and operationalizing work plans to address unacceptable deviations from performance; and
 6. other reasonable management responses.

⁷ The process used in prioritizing risk should be objectively established by the Provider, but may include such considerations as the frequency of a risk occurring, the financial or operational risk associated with a failure, and other relevant factors.

⁸ Mandatory reporting can be accomplished through use of OMIG's Self Disclosure process that can be accessed from OMIG's website.

CONCLUSION

Element #6's requirement for a system for routine identification of risk areas for Providers recognizes the variability of risk by Providers across provider types and even within the same provider type. The system being used by the Provider to identify risk must be implemented and operating.

When assessing Element #6, BOC will review the system for routine identification of risk areas. BOC recommends that the system be documented and that outputs from the system are available for review as evidence that the system is implemented and effective.

If you have any questions on this *Compliance Guidance*, or any compliance issue under New York State's mandatory compliance program obligation, please contact the Office of the Medicaid Inspector General's Bureau of Compliance at 518-408-0401 or by e-mail at compliance@omig.ny.gov.

The *Compliance Guidance* should be considered to be a general guidance to assist those subject to the mandatory compliance program obligations set out in § 363-d and Part 521. It does not set out all the points that OMIG will consider or use when assessing if compliance programs meet the statutory and regulatory requirements. OMIG reserves the right to recall or change this *Compliance Guidance* at any time.