I. Purpose

Section 2718 of the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act), requires health insurance issuers (issuers) to submit a medical loss ratio (MLR) report to the Secretary and requires them to issue a rebate to enrollees if the issuer’s MLR is less than the applicable percentage established in section 2718(b) of the PHS Act. The interim final rule implementing MLR requirements was published on December 1, 2010 (75 FR 74864) and modified by technical corrections on December 30, 2010 (75 FR 82277), the final rule implementing MLR requirements (76 FR 76574) and the interim final rule implementing MLR rebate requirements for non-Federal governmental plans (76 FR 76596) were published on December 7, 2011. The MLR regulations are codified at 45 CFR Part 158.

This Bulletin provides MLR guidance on the following topic:

- Reimbursement for Clinical Services Provided to Enrollees (Incurred Claims): Payments to Clinical Risk-bearing Entities.

II. Questions and Answers

REIMBURSEMENT FOR CLINICAL SERVICES PROVIDED TO ENROLLEES (INCURRED CLAIMS) (45 CFR 158.140): Payments to Clinical Risk-bearing Entities

Question #20: Are payments by issuers to clinical risk-bearing entities, such as Independent Practice Associations (IPAs), Physician Hospital Organizations (PHOs), and Accountable Care Organizations (ACOs), incurred claims under 45 CFR 158.140?

Answer #20: Generally, yes. We will consider such payments to be incurred claims provided that both the payment and risk-bearing entity meet all four factors stated here. 45 CFR 158.140 treats payments by issuers to providers as reimbursement for clinical services to enrollees (also referred to as incurred claims), but does not address situations in which issuers pay a third party, such as an IPA, to perform services that are considered provider services when performed by a provider’s medical practice.
Payments to a clinical risk-bearing entity are considered incurred claims if the following four factors are met:

- The entity contracts with an issuer to deliver, provide, or arrange for the delivery and provision of clinical services to the issuer’s enrollees but the entity is not the issuer with respect to those services;
- The entity contractually bears financial and utilization risk for the delivery, provision, or arrangement of specific clinical services to enrollees;
- The entity delivers, provides, or arranges for the delivery and provision of clinical services through a system of integrated care delivery that, as appropriate, provides for the coordination of care and sharing of clinical information, and which includes programs such as provider performance reviews, tracking clinical outcomes, communicating evidence-based guidelines to the entity’s clinical providers, and other, similar care delivery efforts; and
- Functions other than clinical services that are included in the payment (capitated or fee-for-service) must be reasonably related or incident to the clinical services, and must be performed on behalf of the entity or the entity’s providers.

If the entity satisfies this four-part test, payments for clinical services for which the entity takes on the financial risk for utilization as provided in prong two above will be considered incurred claims. Conversely, when an entity takes on only pricing risk, Question and Answer 19 in the July 18, 2011 guidance applies (http://cciio.cms.gov/resources/files/20110718_mlr_guidance.pdf). Q&A #19 addresses payments to third party vendors who pay others to provide clinical services to enrollees and who perform administrative functions. It provides that the entirety of the payment by an issuer to an entity that only takes on pricing risk (e.g., payments to pharmacy benefit managers (PBMs) for retail pharmacy claims) should not be reported as incurred claims.

**Question #21:** Are payments by issuers to such clinical risk-bearing entities that include payment for administrative functions performed on behalf of the entity’s providers incurred claims under 45 CFR 158.40?

**Answer #21:** Yes, if all four factors set forth in Answer #20 are met. For example, a bundled payment to an IPA or similar entity for providing clinical services to enrollees which includes: the IPA processing claims payments to its member providers and submitting claims reports to issuers on behalf of its providers; performing provider credentialing to determine a provider’s acceptability into the IPA network; and developing a network for its providers’ benefit, would be included in incurred claims.

**Question #22:** Are payments by issuers to clinical risk-bearing entities, such as Independent Practice Associations (IPAs), for administrative functions performed on behalf of the issuer, incurred claims under 45 CFR 158.140?

**Answer #22:** To the extent that administrative functions are performed on behalf of the issuer, that portion of the issuer’s payment that is attributable to the administrative functions may not be included in incurred claims (See Questions and Answers 11, 12 and 13 in the May 13, 2011 guidance at http://cciio.cms.gov/resources/files/2011_05_13_MLR_Q_and_A_Guidance.pdf. This is the case regardless of whether payment is made according to a separate, fee-for-service
payment schedule or as part of a global, capitated fee payment for all services provided. For example, payment for processing claims in order to issue explanations of benefits (EOBs) to enrollees and handling any stage of enrollee appeals would not be included in incurred claims. Payments for non-clinical services for which the contract between the IPA and the issuer contains a “clawback” provision are not considered incurred claims for MLR reporting purposes.