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September 22, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-6074-NC
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: <http://www.regulations.gov>

RE: Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (CMS-6074-NC) – AHIP Comments

Dear Mr. Slavitt:

America's Health Insurance Plans (AHIP) appreciates this opportunity to offer comments and recommendations in response to the Centers for Medicare & Medicaid Services' (CMS') August 23, 2016 request for information (RFI): Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (81 Fed. Reg. 57554) and accompanying letter to end-stage renal disease (ESRD) providers.

AHIP and our members support access by all consumers to affordable health coverage without regard to health status and through the coverage program that best meets their needs based on their specific circumstances and eligibility. We also recognize the important role that many entities, such as Ryan White HIV/AIDS Programs and other third-party entities recognized in CMS guidance, play in providing financial assistance for consumers. Our comments are related to the specific and widespread abuse of third-party payments by certain providers, institutions, and non-profit entities that are steering patients eligible for or receiving Medicare and/or Medicaid benefits into individual market plans (both on-and-off the Marketplace) for the primary purpose of obtaining higher reimbursement.

We commend CMS for addressing this serious problem. Over the last three years our member health plans have seen a significant increase in the types of activities outlined in the RFI, including inappropriate third-party premium payments and copay assistance programs such as prescription drug coupons. Many arrangements involve ESRD providers and related foundations, but they also extend to a range of other providers and entities. They mirror practices that are prohibited in Federal health care programs under the anti-kickback and civil

September 22, 2016

Page 2

monetary penalty (CMP) laws as a result of the adverse consequences for vulnerable beneficiaries and market stability.

In many cases, these practices are harming patients and undermining the individual market by skewing the risk pool and driving up overall health care costs and premiums. While such activity has not been limited to ESRD, our members' experiences have shown that individuals with ESRD are particularly vulnerable. In many cases, third-party organizations (who receive provider funding) directly steer ESRD patients to individual market coverage without any discussion of the options available to them (including Medicare and Medicaid). Moreover, third-party groups often stop paying premiums after the patient has received a kidney transplant and no longer needs dialysis, leaving patients financially exposed and subject to significant penalties in cases where they are receiving premium tax credits under the Affordable Care Act (ACA) for which they are not eligible.

In the Appendix to our detailed comments, we provide examples of inappropriate steering that is taking place today. We also provide data from plans that illustrate the significant growth in the number of individual market enrollees who are receiving dialysis and the impact of this growth on health care spending. For example, some plans have seen claims for dialysis services more than double in one year. In fact, one plan saw its spending on ESRD services increase more than twenty-fold, from *\$1.7 million in 2013 to \$36.8 million in 2015*. Similarly, for other plans, enrollment of individuals with ESRD has increased by 200-500% over a period of only one to three years.

These trends demonstrate the serious and significant nature of the problem. CMS must take immediate action before the start of the 2017 open enrollment period to address these abuses. Given the potential for continued harm to patients and to the stability of the individual marketplace, CMS has "good cause" to find that the notice-and-comment rulemaking process would be "impracticable, unnecessary, or contrary to the public interest" and should adopt an interim final rule (IFR) to curtail these harmful practices. See 5 U.S.C. § 553(b).

In our detailed comments below, we discuss a variety of legal authorities pursuant to which CMS can take the steps necessary to prohibit these activities and impose sanctions on those who engage in such tactics. In summary, we recommend that CMS immediately issue an IFR effective for 2017 that:

1. Prohibits direct and indirect premium payments by providers to entities in which the provider has a financial interest by using CMS' broad rulemaking authority under Medicare and Medicaid;
2. Confirms that certain third-party payments are prohibited under the Civil Monetary Penalties (CMP) law;

September 22, 2016

Page 3

3. Considers health care providers out of compliance with Conditions of Coverage if they fail to provide information to consumers on their full range of coverage options;
4. Interprets Medicare private contracting requirements in ways that discourage intentional steering between markets;
5. Clarifies plan authority to reject certain third-party payments and establishes that federal rules supersede state guidance;
6. Revises guaranteed availability and renewability requirements for Medicare-eligible individuals;
7. Modifies individual market rules to prevent inappropriate steering of Medicaid enrollees to marketplace coverage;
8. Increases transparency of third-party payments; and
9. Utilizes additional regulatory and operational tools to address third-party payments.

Finally, we recommend that CMS issue a new RFI on another concerning area that falls under third-party payments: the growing use of pharmaceutical manufacturer drug coupons, co-pay cards, and related charity programs.

Again, thank you for the opportunity to provide comments, data and other information in support of this RFI.

Sincerely,



Matthew Eyles
Executive Vice President
Policy and Regulatory Affairs



Julie Miller
General Counsel

AHIP Detailed Comments & Recommendations

1. Prohibit Direct and Indirect Premium Payments by Providers to Entities in which the Provider has a Financial Interest by Using CMS' Broad Rulemaking Authority under Medicare and Medicaid

We strongly recommend that CMS utilize its broad rulemaking authority to prohibit providers from funding premiums directly or indirectly through contributions to third-party entities. It is critical to address, as the Department of Health and Human Services Office of the Inspector General (OIG) has done in advisory opinions, indirect premium payments made via third parties. It is an inherent conflict of interest for providers to make payments that incentivize individuals to obtain and maintain coverage that will ultimately benefit the provider. CMS should take action to prevent such activity from occurring.¹ Failure to do so gives providers that otherwise “agree” to Medicare or Medicaid reimbursement rates an optional higher payment amount based on subsidizing the premium in the private market.

We believe CMS has the clear authority through its general rulemaking authority as well as through its Conditions of Participation (CoP) requirements for Medicare and its provider enrollment rules for Medicare and Medicaid to prohibit such direct or indirect payments by providers. The threat of discontinuing Medicare and Medicaid payments could be an effective means to curtail activities that undermine the quality and safety of care for individuals entitled to or eligible for Medicare or Medicaid. The statutory bases for CMS' authority to take action are described below.

First, Sections 1102 and 1871 of the Social Security Act (“SSA”), which are codified at 42 U.S.C. §§ 1302 and 1395hh, provide general authority for the Secretary to prescribe regulations as necessary for the efficient administration of the Medicare program. CMS relied upon these authorities to promulgate the Patients' Rights Condition of Participation, which is applicable to all Medicare and Medicaid participating hospitals and contains standards that ensure minimum protections of each patient's physical and emotional health and safety. See 71 Fed. Reg. 71378 (Dec. 8, 2006).

Second, Section 1866(j) of the SSA, codified at 42 U.S.C. § 1395cc(j), provides specific authority with respect to the enrollment process for providers and suppliers. The Secretary could, under this authority, include a requirement in 42 CFR Part 424, Subpart P (Requirements for

¹ In the context of the Medicare Advantage and Medicare Prescription Drug Benefit Programs, CMS has recognized the potential conflict of interest that a provider may have and requires “that any assistance provided to a beneficiary by a contractual, co-branded, or otherwise affiliated provider, results in a plan selection that is always in the best interest of the beneficiary.” Medicare Marketing Guidelines at § 70.11.1. In the individual market context where providers are giving direct or indirect premium support to influence coverage decisions, the conflict of interest is real as is the concern that the individual's coverage selection may not be in their best interest.

September 22, 2016

Page 5

Establishing and Maintaining Medicare Billing Privileges), to prohibit, as a condition of enrollment and payment, third-party payment of premiums (either directly or indirectly) to a qualified health plan on behalf of a person who is entitled to or eligible for Medicare.

Third, Section 1881(b) of the SSA, codified at 42 U.S.C. § 1395rr(b), provides that the “Secretary shall by regulation prescribe” requirements “for institutional dialysis services and suppliers” to be eligible for Medicare payment. Pursuant to this and other authorities, CMS promulgated Conditions for Coverage for End-Stage Renal Disease Facilities establishing “conditions for coverage that dialysis facilities must meet to be certified under the Medicare program.” 73 Fed. Reg. 20370 (April 15, 2008). The purpose of such conditions “is to protect dialysis patients’ health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis facilities.” *Id.* at 20372 (emphasis added). In addition, the Conditions of Coverage include a focus on patient’s rights, including the right to “be informed about and participate, if desired, in all aspects of his or her care.” 42 C.F.R. § 494.70. Such rights of information and participation are meaningless if the facility at which the patient is receiving care is using its trusted position to cause the patient to make health care coverage decisions in the provider’s financial interests without complete information regarding all available coverage options.

The Secretary could, under this authority, include a requirement in 42 C.F.R. Part 424, Subpart C (Claims for Payment), to prohibit, as a Condition of Payment, third-party payment of premiums (either directly or indirectly) to a qualified health plan (QHP) on behalf of a person who is entitled to or eligible for Medicare. Such an approach would also impact activities directed at individuals eligible for or enrolled in Medicaid since CMS regulations at 42 C.F.R. § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.²

Fourth, Section 1902(a)(27) of the SSA, codified at 42 U.S.C. § 1396a(a)(27), provides general authority for the Secretary to require provider agreements under Medicaid State Plans with every person or institution providing services under the State Plan. This broad authority would permit the Secretary to revise 42 C.F.R. § 431.107 (required provider agreement) to ensure that that Medicaid providers and institutions do not inappropriately steer Medicaid recipients away from the Medicaid program for purposes of obtaining higher reimbursement.

² Such concerns are not, of course, limited to the ESRD context. Section 1861(e)(9) of the SSA, which requires hospitals to “meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individual,” provides the basis for including a similar requirement in the hospital conditions of participation. See also 77 Fed. Reg. 29037 (May 16, 2012) (Noting, with respect to hospital conditions of participation that the “purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals.” *Id.*

September 22, 2016

Page 6

This provision would not run afoul of 1902(a)(25)(G)³ insofar as a Medicaid enrollee may be dual enrolled in a QHP. The restriction would be on the Medicaid-enrolled provider directly or indirectly paying the premium or cost sharing of such an enrollee.

2. Confirm that Certain Third-Party Payments are Prohibited under the CMP Law

Under section 1128A(a)(5) of the SSA, codified at 42 U.S.C. § 132a-7a(a)(5), “any person” who offers or transfers to an individual eligible for Medicare or Medicaid any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier any item for which payment **may** be made under Medicare or Medicaid, is subject to CMPs. In an August 2002 Special Advisory Bulletin, the OIG noted the “broad language of the prohibition and the number of marketing practices potentially affected”. 65 Fed. Reg. 55844 (Aug. 30, 2002).

We believe that the CMP statute is sufficiently broad to prohibit third-party premium payments for individuals eligible for Medicare or Medicaid to enroll in an individual market plan. First, the statute broadly applies to “any person.” Second, premium payments are clearly remuneration within the meaning of the statute. Third, where the services at issue are eligible for payment under Medicare or Medicaid, the “may be made” requirement is satisfied where the individual is entitled to benefits under Medicare or Medicaid.

The limited situations where the OIG has concluded that such payments pose a low risk for fraud and abuse (e.g., independent charity assistance programs) are not present here. See e.g., OIG Advisory Opinion Nos. 06-04 and 06-04A. We note that, on May 2, 2000, the OIG proposed a new safe harbor that would have protected Medigap premium payments for beneficiaries with ESRD. See 65 Fed. Reg. 25460 67 Fed. Reg. 72896 (December 9, 2002). The OIG ultimately withdrew the proposed safe harbor noting:⁴

- The CMP statute targets corruption of the provider selection process. Since any exception would be permissive, any ESRD facility that did not pay premiums for financially needy patients would likely lose business. In short, the exception would promote the very conduct the statute prohibits: the offering of remuneration to influence the selection of a provider.

³ Under this section, the State Plan must provide that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1167(1)], a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual’s behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this subchapter for such State, or any other State.

- Patients would not only be influenced to select ESRD facilities that buy them supplemental health insurance, but would be “locked in” to those facilities, since changing facilities would jeopardize their supplemental insurance for all services, including substantial non-ESRD services.
- Creating an exception for direct premium payments by ESRD providers would create demands for additional exceptions for comparable payments by other health care providers and would potentially increase federal expenditures and Medigap premiums.
- It is to a provider’s financial advantage to pay the Medigap premium whenever the premium is less than the expected copayments. Thus, the insurer will always lose money on these policies, as the amount paid out to the provider will always exceed the premiums received. This phenomenon—adverse selection— will likely cause insurers to raise premiums for all other enrollees to cover the losses.

The OIG’s rationale is equally applicable in this context where the third-party premium payments benefit the providers who make them, directly or indirectly, but no one else. Not the enrollee, the issuer or providers that do not engage in such activity.

3. Consider Health Care Providers Out of Compliance with Conditions of Coverage if They Fail to Provide Information to Consumers on their Full Range of Coverage Options

We fully support efforts to ensure patients are enrolled in health care coverage that best meets their needs. For some individuals, this may be Medicare’s ESRD benefit. For others, it may be Medicaid. For those who do not meet the eligibility requirements for Medicare or Medicaid, health plans are available in the individual market that offer the range of essential health benefits (EHBs) required under the ACA, including coverage for dialysis treatment. We are very concerned that the steering practices that are the subject of the RFI have significant, negative impact on consumers, including: late enrollment penalties under Part B; lack of immunosuppressant coverage under Part B if the kidney transplant is provided outside the Medicare benefit; and implications for other care needed outside dialysis treatment due to lack of health insurance coverage.

It is important to note that the health care providers who stand to benefit most from private insurance coverage are uniquely positioned to steer patients towards both individual market plans and the charitable organizations that pay the premiums for those plans. Under the Conditions of Coverage for ESRD facilities, CMS requires every dialysis facility to employ a renal social worker, 42 C.F.R. § 494.140(d), who works with patients to address their psychosocial needs and often assists them with issues related to their health insurance coverage. 42 C.F.R. § 494.80(a)(7); see also 73 Fed. Reg. 20370, 20424 (noting that commenters to the proposed rule on Conditions of Coverage for ESRD facilities indicated that renal social workers are often used

to perform activities related to insurance coverage). The charitable organization that provides premium support for ESRD members explicitly relies on this social worker⁵ as the conduit for patient access to its support programs. Indeed, this organization will not accept applications from individuals directly and, instead, requires every individual seeking premium support to go through the social worker or other qualified staff at their dialysis facility.⁶ Because every dialysis facility maintains staff who work with patients to address insurance coverage issues and serve as the sole conduit for certain premium support programs, these providers are in a clear position to steer patients towards the health plans that are known to provide higher reimbursement and to the charitable programs that will allow providers to maximize their reimbursement by paying for private health insurance coverage.

CMS requires providers or health plans to provide clear and accurate written information to Medicare beneficiaries in a variety of matters related to coverage and payment. Thus, Medicare Advantage plans “are responsible for ensuring that beneficiaries are fully informed of the benefits covered under the contract as part of their marketing material, evidence of coverage, and summary of benefits,” and all marketing materials are subject to review and approval. 70 Fed. Reg. 4588, at 4690 (Jan. 28, 2005) (promulgating 42 C.F.R. § 422.80). Likewise, before any private agreement can be entered into between a physician and a beneficiary under Section 1802(b) of the Act (42 U.S.C. § 1395a(b)(2)), the physician must obtain a signed consent from the beneficiary that they understand that Medicare will not cover or pay for services provided by the physician.⁷ Providers are required to obtain a signed advance beneficiary notice (ABN) that fully informs the beneficiary of their financial liability for non-covered services, before the beneficiary incurs liability for the service. All of these requirements protect individuals from making coverage decisions or incurring significant financial liability without the benefit of clear and accurate information from parties that may have a financial interest in the outcome of the beneficiary’s decision.

In this context, a provider is either agreeing to pay premiums in a specific plan or making a referral with the expectation that another party will agree to pay a premium for an individual market plan. In many cases, individual patients being referred for such coverage would clearly be eligible for Medicare or Medicaid and the coverage decision thus has significant consequences regarding the suitability of coverage or the possibility of forgoing greater financial assistance or benefits from the Medicare or Medicaid program. However, there is no specific obligation that providers or their employed social workers have to provide clear and accurate

⁵ The organization indicates that other qualified staff at a dialysis facility can perform this function.

⁶ Appendix, Example 2

⁷ Among other requirements, the contract must be in writing and signed by the beneficiary “before any item or service is provided pursuant to the contract,” may not be “entered into at a time when the Medicare beneficiary is facing an emergency or urgent health care situation,” and must inform the beneficiary of “the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this title.” 42 U.S.C. §1395a(b)(2).

September 22, 2016

Page 9

information about the individual's options or alternatives when they recommend or make such referrals for coverage.

We recommend CMS consider health care providers out of compliance with Conditions of Coverage if they fail to provide information to consumers on their full range of coverage options. In addition, CMS should require these social workers to provide consumers with an overview of all health insurance coverage options including any negative consequences of different options for consumers. We recommend CMS develop a model notice that provides individuals with information on how to contact the Medicare program directly by phone or via Internet access, and clearly indicates the consequences of not enrolling in the Medicare ESRD benefit.

4. Interpret Private Contract Requirements in Ways that Discourage Intentional Steerage between Markets

The offer to fund health care coverage premiums in exchange for forgoing Medicare coverage appears to be, in effect, a private contract. We therefore urge CMS to consider its authority to impose the private contract requirements at 42 C.F.R. Part 405, Subpart D, on physicians and practitioners who directly or indirectly make premium payments for individual market plan coverage on behalf of Medicare beneficiaries.

Under Section 1802 of the SSA, codified at 42 U.S.C. § 1395a, a physician or practitioner may enter into a private contract with a Medicare beneficiary for a service that would otherwise be covered under Medicare. Any such private contract must be in writing, signed by the beneficiary, and include that the beneficiary:

- (i) agrees not to submit a claim (or to request that the physician submit a claim) under Medicare for the services;
- (ii) agrees to be responsible, whether through insurance or otherwise, for payment of the services and understands that no reimbursement will be provided under Medicare;
- (iii) acknowledges that the Medicare payment limits do not apply to amounts that may be charged for the services;
- (iv) acknowledges that Medigap plans do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under Medicare; and
- (v) acknowledges that the Medicare beneficiary has the right to have such services provided by other physicians or practitioners for whom payment would be made under Medicare.

Notably, a private contract is null and void if it is entered into at a time when the beneficiary is facing an emergency or urgent health care situation. Section 1802(b)(2)(A)(iii). See also 42 C.F.R. § 405.415(k). Moreover, a physician or practitioner entering into at least one private

September 22, 2016

Page 10

contract must opt out of Medicare for at least a two-year period, and continue the opt-out for successive two-year periods unless the opt-out is cancelled. 42 C.F.R. § 405.405(b).

5. Clarify Plan Authority to Reject Certain Third-Party Payments and Establishes that Federal Rules Supersede State Guidance

Under 45 C.F.R. § 156.1250, health plans are required to accept third-party premium and cost-sharing payments from the following third-party entities: Ryan White HIV/AIDS programs; Indian tribes, tribal organizations, or urban Indian organizations; and a local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf. CMS has also issued related guidance in the form of Frequently Asked Questions (FAQs) and official letters to Members of Congress and others.⁸

We urge CMS to clarify these regulations and related guidance documents by making clear that health plans may deny any third-party payments that are outside the federal requirements and that these requirements supersede any state guidance to the contrary. At a minimum, we recommend that CMS revise its existing FAQ from 2/7/14⁹ by providing further clarification of acceptable and unacceptable foundation entities as well as examples of allowed and disallowed payments. Guidance on the following key areas would also support the appropriate application of these payments moving forward:

- Outline clear guidelines for how a foundation must “market” its assistance to ensure that individuals are meeting financial criteria as opposed to targeting enrollees based on health status.
- Require proportional enrollment across health plans to prevent risk pool issues.
- Allow health plans to reject premium payments if an individual is not enrolled for the entire year.

⁸ See, for example: <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf>; <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf>

⁹ See FAQ (2/7/14) available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf>. Q2. Does the November 4, 2013 FAQ apply to QHP premium and cost sharing payments on behalf of QHP enrollees from private, not-for-profit foundations? A2. No. The concerns addressed in the November 4, 2013 FAQ would not apply to payments from private, not-for-profit foundations if: (a) they are described in Question 1, or (b) if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees’ health status. In situation (b), CMS would expect that premium and any cost sharing payments cover the entire policy year.

6. *Revise Guaranteed Availability and Renewability Requirements for Medicare-Eligible Individuals*

A significant number of individuals steered into individual market coverage are also entitled to, eligible for, or enrolled in Medicare. Unlawful steering of Medicare-eligible beneficiaries into the individual market results in higher premiums for all individuals enrolled in the individual market and in turn increases the amount of subsidies for Marketplace plans. Further, such unlawful practices expose consumers and health plans to Medicare penalties. Medicare beneficiaries face penalties for receiving subsidies (i.e., premium tax credits) to which they were not entitled. Health plans also face Medicare anti-duplication penalties.

CMS' current interpretation of the guaranteed availability and renewability provisions of the Public Health Service Act (PHSA) (as modified by the ACA) has created an unnecessary and untenable conflict between an issuer's PHSA obligations and its obligations under Medicare.¹⁰ To resolve this conflict, CMS should revise its interpretation of the guaranteed availability and renewability requirements to recognize that issuers are not required to issue or renew individual health insurance coverage to individuals entitled to, eligible for or enrolled in Medicare because doing so conflicts with Medicare's anti-duplication requirements. See SSA Section 1882(d), codified at 42 U.S.C. § 1395ss(d).

The ACA market reforms are specifically designed to provide coverage for those consumers outside of the qualifications for the Medicare and Medicaid programs. For example, the 3-1 age rating bands do not encompass ages greater than 65, and individuals who are enrolled in Medicare are not eligible for advance premium tax credits (APTC). Because Congress made a specific policy judgment to afford individuals with ESRD access to coverage under the Medicare program, the program did not contemplate shifts from Medicare to individual market coverage. Even CMS' own messaging to on www.healthcare.gov provides "advice" to Medicare beneficiaries that they need not purchase an individual market QHP on an Exchange and goes on to state that "it is against the law" for someone with Medicare to purchase a QHP on an Exchange.

We strongly support a revision to the existing guaranteed renewability requirements as discussed in the proposed 2018 Notice of Benefit and Payment Parameters¹¹ that would prohibit the renewal of a Medicare eligible individual or Medicare beneficiary at the end of the plan year. For the Marketplace population, we recommend that the Marketplace provide these Medicare-eligible enrollees with information about their Medicare eligibility and support a transition to their enrollment in the Medicare program. For the population off the Marketplace, health plans

¹⁰ See FAQs A.1-A.4 and B.1. and B.2., at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_8-28-14_v2.pdf

¹¹ 81 Fed. Reg. 61456 (Sep. 6, 2016).

September 22, 2016

Page 12

would request information from their enrollees regarding their eligibility for Medicare coverage. We recommend that CMS clarify that, during any plan year in which an enrollee becomes Medicare-eligible, their individual market coverage is secondary to their Medicare coverage. We believe this approach would remove the incentive for providers and others to inappropriately steer these individuals into commercial insurance coverage in order to obtain higher reimbursement. We will discuss this issue further in our forthcoming comments on the 2018 Payment Notice.

In addition, we strongly support a change in the interpretation of guaranteed availability as it relates to Medicare. CMS' regulation already provides that guaranteed issue is not required when it is otherwise prohibited under federal law. We recommend that CMS interpret its own rule to include the Medicare anti-duplication requirement as "federal law." Because issuers are prohibited from marketing this coverage to individuals with Medicare Part A or B, issuers should not be required to enroll individuals without the opportunity for screening individuals for Medicare Parts A or B (or having the Marketplaces carry out such screening and recommend enrollment in the appropriate federal program).

We recommend that opportunities to identify and educate Medicare and Medicaid eligible individuals prior to their enrollment continue to be explored. It would be better for individuals (and issuers) if individuals enrolled in Medicare or Medicaid when initially eligible – and the penalty structure underscores the fact that this was the intent of the program. We discuss potential changes to the Marketplace application later in our comments.

We also urge CMS, for individuals inappropriately steered to Marketplace plans, to take steps to ensure continuity of coverage in transitioning these individuals to Medicare and Medicaid. For example, CMS should consider allowing such individuals to enroll in Medicare without late enrollment penalties on the basis that these persons were not fully informed of the ramifications of their decision. This could be done as a one-time exception for 2017.

7. Modify Individual Market Rules to Prevent Inappropriate Steering of Medicaid Enrollees to Marketplace Coverage

Our members report a growing number of third-party payments for enrollees who are dually enrolled in Medicaid and Marketplace coverage. This scenario is contrary to the intent of the ACA, which established a central Marketplace to determine eligibility for Medicaid, CHIP and Marketplace coverage and enroll the individual in the applicable program.¹² Dual enrollment was

¹² Section 1413(a) of the Affordable Care Act. (a) ...residents of each State may apply for enrollment in, receive a determination of eligibility for participation in, and continue participation in, applicable State health subsidy programs. Such system shall ensure that if an individual applying to an Exchange is found through screening to be eligible for medical assistance under the State Medicaid plan under title XIX, or eligible for enrollment under a State

September 22, 2016

Page 13

not contemplated, except in the limited scenario where a consumer enrolls in coverage and is eligible for APTC while their Medicaid eligibility is being determined.¹³

We appreciate that the existing Marketplace application screens for Medicaid eligibility and recent periodic data matching processes check state Medicaid systems for consumers who are potentially dually enrolled in Medicaid and Marketplace coverage and receiving APTC and/or cost-sharing reductions. We understand that CMS will soon take action to end their APTC, however, we recommend that CMS go further by terminating coverage for these individuals to avoid duplicate coverage and reduce incentives for improper steering.

As an alternate approach, to eliminate the incentive for providers to steer Medicaid enrollees into individual market coverage, we recommend that CMS permit health plans to modify the reimbursement rate to the provider to match Medicaid if the member is dually enrolled. We recommend CMS revisit existing FAQs on third-party liability and coordination of benefits in relation to Medicaid which currently prohibits issuers from taking this approach. FAQ #2 indicates that the Social Security Act as amended¹⁴ “prohibits health insurers from taking an individual’s Medicaid status into account in enrollment or payment decisions.”¹⁵ However, such action is critical given the impact on state Medicaid funding as well as the negative impact on consumers who would potentially owe premium tax credit once determined eligible for Medicaid and on issuers that cannot rely on Medicaid payments for these dual enrollees.

8. Increase Transparency of Third-Party Payments

CMS seeks input on how premium payments are made by third parties and how to increase transparency of such payments.¹⁶ Per the recommendations we outlined above, we believe CMS’

children’s health insurance program (CHIP) under title XXI of such Act, the **individual is enrolled for assistance under such plan or program** (*emphasis added*).

¹³ 45 C.F.R. 155.345(e) requires Exchanges to treat someone eligible for APTC while their Medicaid eligibility is being determined.

¹⁴ A State plan for medical assistance must—...provide...that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, a managed care organization, a pharmacy benefit manager, or other party that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service), in enrolling an individual or in making any payments for benefits to the individual or on the individual’s behalf, from taking into account that the individual is eligible for or is provided medical assistance under a plan under this title for such State, or any other State;

¹⁵ See “Medicaid and CHIP FAQs: Identification of Medicaid Beneficiaries’ Third Party Resources and Coordination of Benefits with Medicaid” Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/faq-09-04-2014.pdf>. Updated September 11, 2014.

¹⁶ See 81 Fed. Reg. 57554, 57557 (Aug. 23, 2016): “Is the payment of premiums and cost-sharing commonly used to steer individuals to individual market plans, or are other methods leading to Medicare and Medicaid eligible individuals being enrolled in individual market plans? Specifically, how often are issuers receiving payments directly from health care providers and/or provider affiliated organizations? Are issuers capable of determining

September 22, 2016

Page 14

focus should be on finalizing regulations that will *prevent* inappropriate third-party payments and steering. We also believe increased transparency is critically important to assure visibility and proper oversight of such payments. Unfortunately, today, there is no systematic way of capturing this information. Rather, these activities are often identified “after-the-fact” when health plans see unusual spikes in enrollment trends or claims costs in certain geographic areas (see Appendix for examples). Such a post hoc approach is insufficient for identifying issues that have the potential to greatly harm consumers. Instead, greater transparency is needed to ensure that individuals are not being steered inappropriately into coverage that may not be in their best interest. Such an approach is also necessary to prevent disruption to the individual market risk pool and an increase in overall health care spending.

Specifically, we urge CMS to:

- Require third-party organizations that are making premium or cost sharing payments on behalf of individual market enrollees to report certain information to CMS and attest that they meet the requirements as specified by CMS guidance and FAQs. Specifically, we recommend CMS collect the following information:
 - Number of consumers for whom the entity makes payments (by state or rating area);
 - Volume of payments over a specified time period;
 - Contact information;
 - Tax ID and filing status;
 - Governance (e.g., leadership, members of Board of Directors, principal shareholders, etc.);
 - Funding sources;
 - Information on relationships with provider organizations (financial or other); and
 - Information on relationships with pharmaceutical companies (financial or other).
- Impose new transparency requirements on providers. In instances where providers donate to third-party organizations and where there is a potential downstream reimbursement interest, providers should be required to report such payments to CMS. CMS could implement these requirements through revisions to its existing rules regarding conditions of participation and provider enrollment (discussed above).

when third party payments are made directly to a beneficiary and then transferred to the issuer? What actions could CMS consider to add transparency to third-party payments?”

9. Utilize Additional Regulatory and Operational Tools to Address Third-Party Payments

We believe CMS' primary focus should be on *preventing* inappropriate third-party payments. We also recommend the following actions:

CMS should Engage the Healthcare Fraud Prevention Partnership (HFPP):

We strongly support CMS' efforts to investigate instances of potential fraud and abuse and agree that collaboration through the HFPP should be a key element of such efforts. Another egregious example of fraud and abuse by third-party sources of health insurance premiums has come to AHIP's attention through conversations within the HFPP. Briefly, recruiters (also known as "body brokers") are paid to identify and recruit individuals with alcohol or drug problems to receive services in facilities known as "sober homes." These recruited individuals are transported, often across the country, to the sober homes and fraudulently enrolled in health plans. Enrollees typically are not aware of their enrollment. The providers in some cases arrange to keep relevant information, such as Explanation of Benefit statements, from the enrollees. Once a consumer is enrolled, the providers charge the targeted health plans for frequent unnecessary and inappropriate urine screening tests and other inappropriate services.

The HFPP has become an important venue for sharing information regarding health care fraud and abuse schemes involving drug abuse, sober homes, and urine screening tests. We suggest that the HFPP could and should deepen its focus on these issues, including cooperation with HFPP members to address the questions raised in the RFI and to identify and combat health insurance premium payment by third parties that are a part of health care fraud and abuse schemes.

CMS should revise the Marketplace application to collect information on providers and screen for Medicare and Supplemental Security Income (SSI) eligibility:

To address inappropriate third-party payments, we recommend that CMS add the following questions to the "Single Streamlined Application" for use by both the Federal and State Marketplaces. In addition, state marketplaces should be required to include the following questions if they have developed their own state-specific application.¹⁷ In addition to the changes below, we recommend that when consumers report a life change to the Marketplace, the applicant should be prompted to update their eligibility information for Medicare, Medicaid, and ESRD status.

- Under "Help Applying for Coverage" (p. 11)– Revise question to ask if the consumer was referred by a Medical Provider and capture the provider's name and related

¹⁷ CMS-10400 Attachment A: Electronic Application: List of Items in the Electronic Application to Support Eligibility Determinations for Enrollment through the Health Insurance Marketplace and for Medicaid and the Children's Health Insurance Program, March 7, 2016. Accessed at <http://www.reginfo.gov/public/do/PRAMain>.

information. The existing categories of Navigator, Certified Application Counselor, Non-Navigator assistance personal, agent and broker may miss other types of individuals who are assisting consumers.

- Under “Help Paying for Coverage” (p. 12) – New question could be added, e.g., “Has any organization offered to pay your premium or cost-sharing?” In addition to this or alternatively, the question regarding income (p. 32) could ask about premium or cost sharing assistance (under “O. Other income”).
- Regarding Medicare and SSI (p. 51), the application only asks if an individual currently has Medicare. This question could be expanded to inquire about Medicare and SSI eligibility. An alternative would be to permit plans to request this information.
- Regarding potential eligibility for Medicare due to ESRD, the application could ask whether the individual is currently undergoing treatment for ESRD.

CMS should enhance consumer education regarding third-party payments:

We urge CMS to consider approaches that would help consumers better understand issues around third-party payments, including the type of third-party payments that are allowed and not allowed in the individual market. This could include a model notice that issuers could have the option to provide to enrollees regarding acceptable third-party payments.

10. Issue an RFI on the Impact of Pharmaceutical Manufacturer Coupons, Co-Pay Cards and Charity Programs

We also believe CMS should outline a strategy for ongoing assessment and monitoring of another concerning area of third-party payments – the growing use of prescription drug coupons, co-pay assistance cards, and charity programs. An important first step in that regard is issuing a separate RFI aimed at understanding the scope and impact of these programs.

On the issue of drug coupons, academics have concluded that such programs – while portrayed as a consumer-friendly benefit – actually increase overall costs and drive up premiums:

“Drug coupons have long-term financial consequences, particularly when generic or other lower-cost therapeutic options are available. They lead to unnecessary spending by insurers which is passed on to all patients in the form of

September 22, 2016

Page 17

increased premiums and reduced coverage of other potentially useful health care interventions.”¹⁸

Similar concerns have been raised by the OIG:¹⁹

“Cost-sharing requirements for Federal health care program drugs serve an important role in protecting both Federal health care programs and their beneficiaries. These cost-sharing requirements promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market. While copayment coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries.⁵ The availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices. Excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent.”

Of further concern, the use of coupon programs continues to grow. According to the IMS Institute for Healthcare Informatics, copay cards are used for 8% of all branded prescriptions with use in some expensive specialty drug classes much higher – as high as 70% for multiple sclerosis and rheumatoid arthritis drugs.²⁰

As part of a new RFI that examines the use of coupons, we recommend that CMS include an examination of the practice of pharmaceutical companies donating product to charitable organizations. Such an examination is critical to ensure that these charities are operating as intended and that pharmaceutical companies are not exerting influence over how the charities allocate their funding. A recent analysis²¹ highlights the potential for concern, with the

¹⁸ Alfred Engelberg, October 29, 2015, <http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/>; The Short-Term And Long-Term Outlook Of Drug Coupons; Lara Maggs and Aaron Kesselheim, November 12, 2014 <http://healthaffairs.org/blog/2014/11/12/the-short-term-and-long-term-outlook-of-drug-coupons/>.

¹⁹Office of Inspector General, Special Advisory Bulletin September 2014. https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

²⁰ IMS Institute for Healthcare Informatics. April 2015. Medicines Use and Spending Shifts. https://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf.

²¹ “How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes,” May 19, 2016, available at <http://www.bloomberg.com/news/articles/2016-05-19/the-real-reason-big-pharma-wants-to-help-pay-for-your-prescription>

September 22, 2016

Page 18

significant growth in such charities and the fact that the vast majority of their funding comes from pharmaceutical companies:

“...[P]SI’s revenue grew rapidly, from \$16 million in 2003 to \$128 million last year. In 2014 the charity said just over half its funds came from a single drug company, though it didn’t name the donor. Former employees say it was Novartis; Novartis confirmed it’s given to PSI, but declined to say how much.

The largest copay charity, the PAN Foundation, grew even faster, soaring from about \$36 million in contributions in 2010 to more than \$800 million last year. About 95 percent of PAN’s contributions come from the pharma industry, the charity says; in 2014, five unnamed drug companies kicked in more than \$70 million apiece, according to PAN’s tax filing. With this eager stable of donors, PAN spent just \$597,000 on fundraising in 2014. That’s less than 1 percent of the fundraising expense for similar-sized charities, like the American Cancer Society and the American Heart Association.”

Appendix
Examples of Steering into Individual Market Plans and Individual Market Impacts

CMS seeks information about circumstances in which steering into individual market plans may be taking place as well as the impact on the individual market.²²

AHIP has aggregated and de-identified information from our member health insurance plans with the understanding that it would be included in our comments to CMS. Information on the financial impact was provided through an analysis of certain health insurance claims in the individual market from 2013 to the present. In certain examples information on the increase of per member per month (PMPM) spending is included. Information on steering of potential Medicare and Medicaid eligible or enrolled individuals to individual market coverage (both on and off the Marketplace) was obtained through a series of health plan interviews conducted by health plan staff during investigation of improper payments throughout 2015 and 2016.

It is clear from our examples the significant financial impact these third-party payments have had as well as evidence that consumers are being enrolled without understanding the negative financial impact of enrolling in private coverage (late Part B enrollment penalties, lack of coverage for certain drugs post Kidney transplant). Below, we also outline examples of other third-party activity outside ESRD.

The impact of the addition of any single individual to a risk pool ultimately depends on the relationship between the amount of premiums that the member pays to the health plan (or that are paid on the member's behalf) and the amount of covered medical expenses incurred by the member. When an individual incurs medical expenses that substantially exceed the premiums paid, the resources available in the risk pool become depleted at a much faster rate than they otherwise would. Although there are a number of activities that health plans can take to control the medical expenses incurred by such individuals (e.g., care management, value-based provider arrangements), the addition of such individuals to a risk pool will inevitably lead to increased rates for everyone individual who is covered by the same risk pool. The potential impacts of such activity on the individual market can be very significant, especially when activity is focused on a vulnerable, high-cost population such as those with ESRD and when there is a concerted effort to move all such individuals into a single plan in the individual market.²³

²² 81 CFR 57557. "In what types of circumstances are healthcare providers or provider-affiliated organizations in a position to steer people to individual market plans? What impact is there to the single risk pool and to rates when people enter the single risk pool who might not otherwise have been in the pool because they would normally be covered under another government program? Are issuers accounting for this uncertainty when they are setting rates?"

²³ According to MedPAC, in 2014, about 383,000 beneficiaries with ESRD on dialysis were covered under fee-for-service (FFS) Medicare representing spending that totaled \$11.2 billion a 1% increase over 2013. MedPAC, Report to the Congress: Medicare Payment Policy, March 2016.

Typically, health plans will see unusual spikes in claims for services such as dialysis services. In investigating this activity and talking with their members, concerning information has been discovered regarding the circumstances under which individuals have been enrolled. Several examples are provided below.

Example One: This plan had \$8 million in paid claims for dialysis services in 2014. *In 2015, this figure more than doubled to \$19.3 million. Projected paid claims for 2016 will be \$29.5 million.* In investigating these trends, the plan was able to identify numerous individuals whose premiums had been paid for by the American Kidney Fund (AKF). In discussing the circumstances of their enrollment process with these members, a strikingly similar pattern was identified:

- Members who are approached for financial assistance usually are receiving services from a dialysis center owned by contributors to the AKF.
- “Enrollment Counselors” or “social workers” at these dialysis facilities approach patients about financial assistance with their health care premiums. These “enrollment counselors” offer no information about Medicare eligibility to members. In several cases members were not aware that they were Medicare eligible until they were later told by the health plan.
- The AKF would pay premiums for these Medicare-eligible enrollees with a check. However, more recent information indicates that the AKF is now giving members a pre-paid debit card to pay their premium. Such payments cannot be tracked by health insurance plans, making it difficult to assess the extent of these arrangements.
- When asked about bills for cost-sharing or other out of pockets cost, members are advised to ask the dialysis provider to bill them. In most cases the members never receive bills or they are waived.
- If members receive a kidney transplant—and are no longer in need of dialysis services—the AKF will no longer pay their premiums. One member who became eligible for a kidney transplant at a major California hospital system was told by the social worker at the hospital that many of her clients have been on the AKF premium support program and were later surprised to find out they lost the premium support once they had the transplant. This social worker now routinely advises members receiving AKF payments that they will lose their premium payments after a transplant—when these enrollees will be in critical need of health coverage to ensure a successful recovery.

Example Two: The following information is based on a health plan’s interviews with individual members diagnosed with ESRD and were enrolled in Marketplace coverage through the assistance of provider facilities. It is difficult to identify the specifics of the third-party payment process other than to speak with members directly, as the payments are rarely provided directly by the facilities to the insurance carrier. It is not possible to quantify exact damages without

identifying every individual member subjected to this experience; however, the estimated exposure based on investigations done to date is significant. ***For every 100 members that were subject to the scheme described below, estimated costs incurred are approximately \$20 million. The plan has seen its number of enrollees with ESRD increase by 200% from 2015 to 2016.***

- Many members arrive at the facilities directly from the nephrologist or hospital and are met by individuals representing themselves as “social workers.” These “social workers” guide the member and assist in signing them up for the “best” policy. The member is either coached or the social worker completes the application. Other names used for the “social worker” are Benefit Coordinator and Financial Advisor.
- Based on member experiences discussed during these interviews, there is no discussion of the various insurance options or of Medicare coverage. Individuals are immediately guided to specific commercial insurance plans.
- Some members have been instructed to open a checking account in their name. The sole purpose of this account is to receive third-party payer checks. Premium payments are drafted electronically or bank checks are written using the checking account and sent to the insurance carrier. To facilitate this, the member is summoned to the facility’s office to endorse the check. The check is deposited by a representative of the provider. Other members pay directly at the provider’s office. Most members appear to have no understanding as to what is paid on their behalf, or how payment is made.
- Many believe the individual market policy they receive is a supplement to Medicare, and this coverage takes care of any cost-sharing amounts not covered by Medicare. Investigation continues on this issue, but it appears that some individuals are in fact covered by both Medicare and an individual market plan while others are only covered by the individual market plan but believe they have purchased a plan that is “better” than Medicare and includes coverage for all cost-share amounts associated with their ESRD.

Example Three: Another health plan experienced a significant increase in the number of individual market members receiving treatment for ESRD. Comparing June 2015 to June 2016, the percentage of the plan’s individual members receiving dialysis treatments was ***69% higher in 2016*** (based on member months). This trend is expected to result ***in \$10 million more in paid claims by the end of 2016, compared to 2015.***

- This increase was primarily driven by members new this health plan. Specifically, of the 208 plan members who received at least one dialysis treatment as of May 2016, 142 were new members in 2016.
- Of the 142 new individual members, over half (87) were actively enrolled in a Medicaid plan, either offered by the same plan or another managed care organization.
- The AKF paid most/all of the individual premiums for 86 of the 87 active Medicaid members; the exception was a member who had a \$0 premium.

September 22, 2016

Page 22

- In addition to the increased population receiving dialysis treatments, the average paid claim per visit has also increased, from \$2,250 per dialysis visit in 2015 to approximately \$2,500 for 2016.

Example Four: A plan saw its spending on ESRD increase dramatically from *\$1.7 million in 2013 to \$36.8 million in 2015. Spending to date for 2016 is \$28 million. ESRD spend per patient has increased three-fold: from \$59,626 to \$150,599.* Over this time period, the number of patients with ESRD who are enrolled in the plan has *increased by 564%* -- from 28 individuals in 2013 to 186 currently.

Example Five: A large health plan has seen a significant spike of ESRD active members in the individual Marketplace between 2014 and 2016. For example, the percentage of members with ESRD among exchange enrollees is *five times higher in 2016 than in 2014.* Similarly, the percentage of ESRD members enrolled off the Marketplace in 2016 was *more than three times the percentage in 2014.*

Example Six: Another plan conducted an analysis of individuals enrolled in its individual plans who had been diagnosed with end-stage renal disease (ESRD). Through its review, the plan *identified 30 individuals with ESRD who reported Medicaid as their sole payer source when beginning dialysis treatment, but who subsequently enrolled in an individual plan and whose premiums are being paid for by a charitable organization funded primarily by dialysis providers.* Notably, the majority of these Medicaid beneficiaries (25 of 30) also reported being either unemployed or retired due to disability at the start of their dialysis. Nevertheless, the vast *majority (25 of 30) enrolled in the most-expensive level the company's individual plans (Platinum), agreeing to pay premiums averaging over \$900 per month.* Because the financial ability to pay monthly premiums at such levels would disqualify most, if not all, individuals from Medicaid benefits in the state, it is highly unlikely that any of these members would have sought out and enrolled in Platinum plans of their own accord and without some form of steering or promise for premium support. Indeed, even if a Medicaid beneficiary who developed ESRD had the resources to pay such premiums, it is unclear why he or she would opt for the most expensive private health insurance option when comprehensive coverage could be obtained at a far lower premium cost and with far lower exposure to out-of-pocket costs through enrollment in original Medicare and pairing that coverage with a Medicare Supplement plan that covered the Part B deductible and excess charges. For the healthcare provider supplying dialysis, however, the benefit of having that individual covered under a Platinum-level individual plan is manifest given the higher reimbursement rates paid by private health plans.

Example Seven: A health plan discovered that a local Medicaid plan was enrolling members into individual coverage off the Marketplace. Premium payments for the individual market coverage were being made by the Medicaid plan's chief financial officer. As of March 31, 2016, the plan had identified a total of forty members enrolled in its individual market plan through this

September 22, 2016

Page 23

scheme. Thirty-nine of the Medicaid members had been diagnosed with end-stage renal disease, some subsequently required transplants. By June 1, 2016, the plan had paid more than \$11.5 million in claims for just these forty members. The Medicaid plan openly described its strategy in its FY2015-2016 budget as follows: “This program pays existing private or group health insurance premiums for members with existing high-cost medical conditions. Purchasing health coverage for these members helps shift the cost of their medical care to the other insurance carrier...” The Medicaid plan also advertised its program to providers as a way to obtain higher reimbursement for covered services.

Example Eight: Above we highlight fraudulent activity related to “sober homes.” Similarly, a plan has seen widespread fraud and third-party payments by residential treatment facilities providing substance abuse treatment. Many of the individuals enrolled through these programs would be eligible for Medicaid, but they are enrolled in individual coverage off the Marketplace to avoid any eligibility screening. These facilities advertise to out-of-state or homeless people, and then enroll the individuals through the SEP for a “permanent move” even though they do not qualify. The premiums are frequently paid by the residential treatment facility on behalf of the enrollees.

One facility billed this plan \$60 million in claims, most of which were denied after investigation. These facilities often pay premiums and offer financial incentives including rent reductions and waiver of patient responsibilities as long as patients agree to reside at the facility. Investigations consistently show excessive lab fees and falsified billing from these facilities. Recently these residential treatment facilities have started claiming to be “non-profits” to shield themselves from the allegation of financial gain. Any regulation in this area must therefore not rely on an organization’s status as a “non-profit” because that status can be readily manipulated.