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Finding the Rx for Your Patient Assistance Program: Keeping Up with the Competition and with Law Enforcement Trends

*Premier Source Operations Managers
and TC Learning Session*

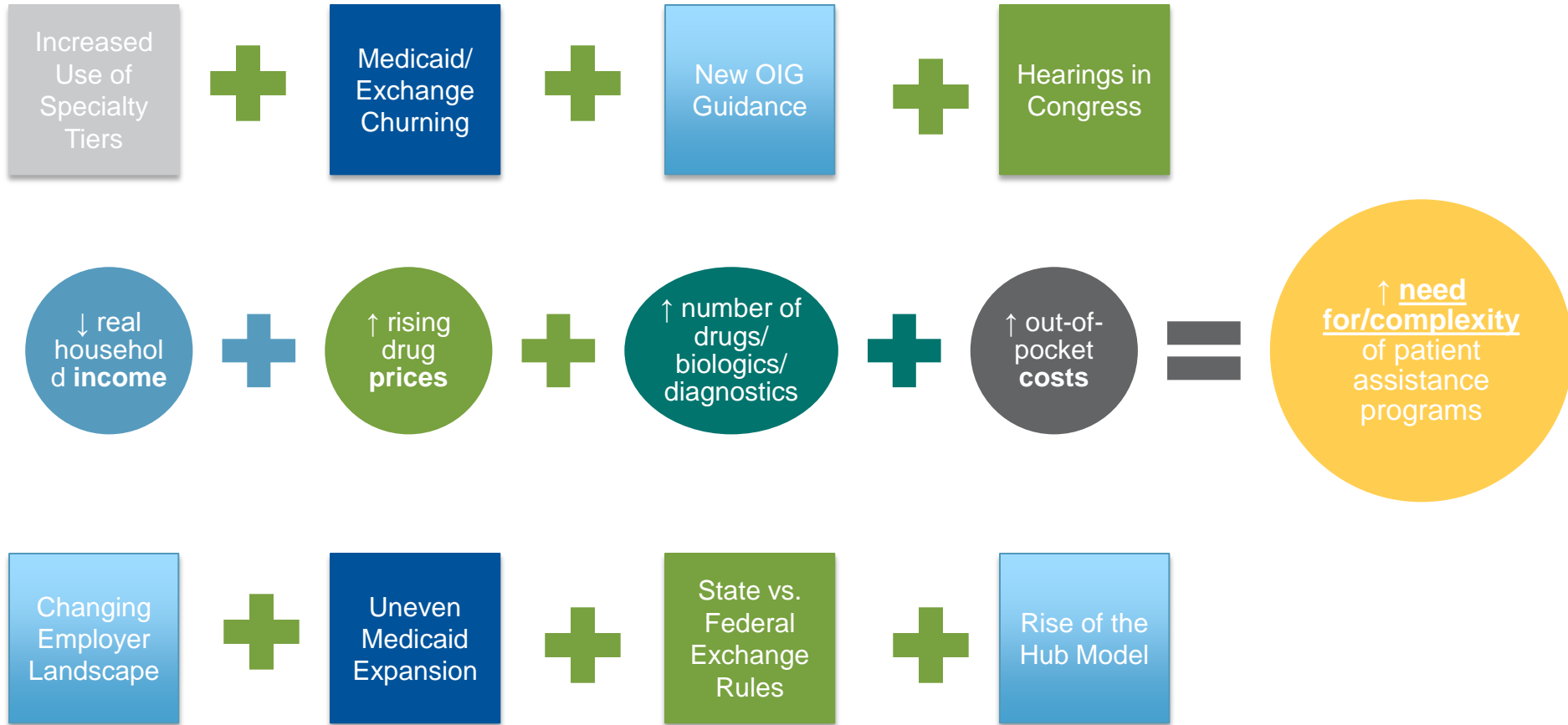
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What is creating the current environment?



Third Party Payment Trends

- UnitedHealthcare Network Bulletin, March 2016:

UnitedHealthcare benefit contracts exclude coverage for any out-of-network lab services for which the provider waives the coinsurance, copayments or deductibles. In addition, routine waiver of coinsurance, copayments or deductibles may be a violation of the Federal False Claims Act, subject to investigation by the Office of the Inspector General and/or any applicable state insurance department's fraud division.

Lab Compliance Continues to Evolve Rapidly

- > There has been explosive growth in molecular and genomic testing over the past decade.
- > These tests raise a host of new issues:
 - No CPT codes assigned
 - Methodology is “research use only” (RUO) or “investigational use only” (IUO)
 - Lack of LCDs / NCDs despite a profusion of tests
 - Diagnostic Testing market and provide costly tests during a period when Medicare carriers may view the test as investigational
 - Commercial insurers issue rapid and reflexive non-coverage policies
 - Potentially high cost of tests to patients

The Latest Wave of OIG Advisory Opinions: What Does It Mean?

OIG Supplementary Special Advisory Bulletin

- > On May 30, 2014, OIG issued a Supplemental Special Advisory Bulletin (“Supplemental Bulletin”) that expanded on its 2005 guidance and focused on the risks for fraud and abuse posed by PAPs operated by independent charities.
- > OIG identified three areas of concern with respect to independent charity PAPs.
 - First, a charity PAP with a narrowly defined disease fund may end up primarily or exclusively funding the products of its donors, which could be an unlawful inducement.
 - Second, defining patient eligibility for PAP assistance with reference to the cost of a particular drug could be evidence of intent to induce the use of that drug rather than an effort to accurately identify and meaningfully address patient financial need.
 - Third, a charity PAP should not provide donors with information that would permit donors to correlate their donations with the volume of their products supported by the PAP.

Fallout from the OIG Supplementary Bulletin

- > The Supplemental Bulletin was followed by an extensive series of OIG Advisory Opinions on PAPs.
- > Between October 26, 2015 and January 13, 2016, OIG issued 14 Advisory Opinions, or modifications or terminations of earlier Advisory Opinions.
- > Thirteen of these concerned PAPs, including eight modified opinions and the termination of two Advisory Opinions.
- > The termination of an Advisory Opinion is an unusual step for OIG to take.
- > In their online archive of Advisory Opinions, which dates back to June 1997, there is only one other terminated opinion.

11-02-2015 PAP Advisory Opinions from OIG:

- [Modification of OIG Advisory Opinion 06-10](#)

(modifies [Advisory Opinion 06-10](#) which concerned a nonprofit, tax-exempt, charitable organization's practice of providing certain therapy management services and assistance with Medicare cost-sharing obligations to financially needy Medicare beneficiaries undergoing medical treatment for certain diseases, to reflect guidance issued on May 21, 2014 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.)

- [Modification of OIG Advisory Opinion 07-18](#)

(modifies [Advisory Opinion 07-18](#) concerning the management by a health care industry consultancy of a charitable organization's arrangements to subsidize patient cost-sharing and premium obligations, and its first modification at [Modification of Advisory Opinion 07-18](#), to reflect guidance issued on May 21, 2014 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.)

12-07-2015 PAP Advisory Opinion from OIG:

- > [Modification of OIG Advisory Opinion 07-11](#)

(modifies [Advisory Opinion 07-11](#), which concerned a nonprofit, tax-exempt, charitable organization's practice of providing financially needy cancer patients with grants to defray their out-of-pocket treatment costs, to reflect guidance issued on May 21, 2014 in the Supplemental Special Advisory Bulletin regarding [Independent Charity Patient Assistance Programs](#).)

12-29-2015 PAP Advisory Opinions from OIG:

- > [Modification of Advisory Opinion 07-06](#) (modifies [Advisory Opinion 07-06](#) which concerned the management by a health care industry consultancy of a charitable organization's arrangements to assist patients with specified chronic diseases with cost-sharing and premium obligations, and its first modification at [Modification of Advisory Opinion 07-06](#), to reflect guidance issued on May 21 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.)
- > [Modification of Advisory Opinion 11-05](#) (modifies [Advisory Opinion 11-05](#) which concerns a nonprofit, tax-exempt, charitable organization's practices of providing vouchers for genetic tests and assistance with cost-sharing obligations for certain genetic tests and prescription drugs for cancer treatment and its first modification at [Modification of Advisory Opinion 11-05](#), to permit earmarking of donations to specific disease states and to reflect guidance issued on May 21 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.

12-30-2015 PAP Advisory Opinions from OIG:

- > [Modification of Advisory Opinion 06-04](#) (modifies [Advisory Opinion 06-04](#), which concerned a nonprofit, tax-exempt, charitable corporation's proposal to provide financially needy Medicare beneficiaries with assistance with premiums and cost-sharing obligations, to reflect guidance issued on May 21, 2014 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.)

01-02-2016 PAP Advisory Opinions from OIG:

- > [Advisory Opinion 15-17](#) (regarding a non-profit, tax-exempt, charitable organization's proposal to provide financial assistance with copayment obligations, health insurance premiums, and insurance deductibles to patients, including Medicare and Medicaid beneficiaries, receiving treatment for [disease state redacted])
- > [Advisory Opinion 15-16](#) (regarding a nonprofit, tax-exempt, charitable organization's proposal to provide assistance with out-of-pocket expenses for outpatient prescription drugs to financially needy insured patients, including, but not limited to, Medicare and Medicaid beneficiaries)

01-06-2016 PAP Advisory Opinions from OIG:

- > [Modification of Advisory Opinion 04-15](#) (modifies [Advisory Opinion 04-15](#) grants provided by a nonprofit, charitable organization to financially-needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies, and its first modification at [Modification of Advisory Opinion 04-15](#), to reflect guidance issued on May 21 in the Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.)

01-20-2016 PAP Advisory Opinions from OIG:

- > [Terminated Advisory Opinion No. 10-06](#) (concerning a patient assistance program that assists underinsured patients with their prescription drug co-payment obligations)
- > [Terminated Advisory Opinion No. 08-17](#) (concerning a nonprofit, tax-exempt, charitable organization's arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with a certain disease)

Other Allowable Support Programs

- **Co-pay Assistance for Medicare/Medicaid:** “cost- sharing subsidies provided by bona fide, independent charities should not raise anti-kickback concerns” (OIG Advisory Opinion 14-11)
 - Also see OIG Advisory Opinion 15-14 (MRI program reimburses contracted providers in full, so no Medicare/Medicaid reimbursement)
- **Lodging/Transportation:** SSA 1128A (“remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs”) See *also* (OIG Advisory Opinion 11-01)
- **Also permissible under, strict oversight:** premium support, incidental expenses, diagnostic imaging

Temporary Free Goods/Services Programs

> **Can manufacturers include Federal healthcare beneficiaries in their commercial temporary free goods/services programs (i.e. quick start or bridge programs)?**

Yes (see OIG Advisory Opinion 15-11)

- ❑ Must have limits in place to prevent overutilization (e.g. patient only eligible for 1-2 goods/services)
- ❑ Not a seeding program (strict guidelines on advertising of the program, insurance must be in place, and alternatives available)
- ❑ Prescriber receives no financial benefit
- ❑ No cost to the Federal government
- ❑ Beneficiary inducement toward a particular provider or supplier must be minimized

Thank you.

- > And thanks to my colleague, Ross Margulies, for his contributions to the presentation materials.
- > For follow-up, please contact:
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