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Health Law UPDATE

October 2014

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HIPAA Corner

FEDERAL UPDATE

OCR Issues Guidance on HIPAA and Same-Sex Marriage

The Department of Health & Human Services, Office for Civil Rights (OCR) released guidance on HIPAA's provisions related to family members, and specifically, lawful same-sex marriages, in light of the U.S. Supreme Court's decision in *United States v. Windsor*, 133 S. Ct. 2675 (2013).

Specifically, the OCR advised that:

- the term spouse includes same-sex spouses who are in a legally valid marriage sanctioned by a state, territory, or foreign jurisdiction (so long as a U.S. jurisdiction would also recognize the marriage);
- the term marriage includes both same-sex and opposite-sex marriages; and
- the term family member includes dependents of same-sex and opposite-sex marriages.

All of these terms apply to legally married individuals, regardless of whether they live in a jurisdiction that recognizes their marriage. This guidance helps covered entities in determining with whom they can share an individual's protected health information.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | Idornfeld@bracheichler.com Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

DOJ Signals Strict Enforcement of 60 Day Rule

The United States Department of Justice (DOJ) recently filed an intervening complaint in an action alleging violations of an Affordable Care Act provision which requires repayment of Medicare and Medicaid overpayments within 60 days of identifying them (the "60 Day Rule"). This appears to be one of the first cases in which the DOJ has sought enforcement of the rule. The Affordable Care Act further provides that a violation of the 60 Day Rule in turn can serve as the basis for further claims under the False Claims Act. The fact that the DOJ requested the maximum penalty allowed under the False Claims Act in its first case enforcing the 60 Day Rule (\$11,000 for each improperly retained overpayment, plus three times the amount of each claim), suggests that regulators may take a harsh stance with respect to suspected violations of the rule.

The case, *Kane v. Healthfirst et al.*, was originally brought as a qui tam action by Robert Kane against his former employer Continuum Health Partners Inc., Healthfirst Inc., New York hospitals Beth Israel Medical Center and St. Luke's-Roosevelt Hospital Center and others. The New York State Attorney General also joined the action as an intervening plaintiff.

The action is pending in the United States District Court, Southern District of New York, under Docket No. 11-2325.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com

CMS Releases ACO Data

The Centers for Medicare & Medicaid Services (CMS) released quality and financial performance results for the accountable care organizations (ACOs) that are part of its Pioneer program and Medicare Shared Savings Program (MSSP). The results show that the 23 reporting Pioneer ACOs improved in three key areas: financial, quality of care and patient care. Pioneer ACOs saved Medicare approximately \$41 million and qualified for \$68 million in shared savings payments. Pioneer ACOs also improved their average performance score for patient and caregiver experience in six out of seven measures. MSSP ACOs also showed improvement in quality of care and patient care, improving in thirty of thirty-three quality measures. However, financial performance was mixed, as only 53 of the 220 reporting MSSP ACOs were on target for shared savings. As a whole, MSSP ACOs saved Medicare approximately \$345 million and qualified for \$300 million in shared savings payments.

Eleven New Jersey MSSP ACOs were included in the data released by CMS; three achieved the shared savings thresholds. Since Medicare ACOs were created in 2010, 18 ACOs serving patients in New Jersey have entered the MSSP.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com Kevin M. Lastorino | 973.403.3129 | klastorino@bracheichler.com

CMS Issues Updated Transmittal on Audits of "Related" Claims

The Centers for Medicare & Medicaid Services (CMS) recently issued an updated transmittal related to its Medicare audit programs in response to an earlier transmittal stating the Medicare Administrative Contractor (MAC), Recovery Auditor and Zone Program Integrity Contractor (ZPIC) should "have the discretion to deny other related claims submitted before or after the claim in question." This transmittal caused significant pushback from the provider and supplier community and CMS rescinded it.

The updated transmittal provides that the MAC and ZPIC have the discretion to deny other "related" claims submitted before or after the claim in question. If documentation associated with one claim can be used to validate another claim, those claims may be considered "related." The updated transmittal provides examples of claims that may be considered "related."

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The MAC and ZPIC must await CMS approval prior to initiating requested "related" claims review. Upon receipt of approval the MAC must post the intent to conduct related claims review on its website within one month of initiation of the review. The MAC, Recovery Auditor and ZPIC are not required to request additional documentation for the related claims before issuing a denial for those claims.

For more information, contact:

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com

CMS Offers Hospitals 68 Cents on the Dollar to Settle Claims Appeals

To clear the massive backlog of inpatient status claims currently pending in the Medicare claims appeal process, the Centers for Medicare & Medicaid Services (CMS) is offering hospitals 68% of the net allowable amount of each claim to any hospital willing to withdraw its pending appeals. CMS is encouraging hospitals to participate in the settlement offer to help alleviate the administrative burden of current appeals on Medicare and the hospitals. To accept the settlement, hospitals must submit the required documents by October 31, 2014. Hospitals that do not accept the settlement will remain in the normal appeal process.

Acute care hospitals and critical access hospitals are eligible to submit settlement requests. However, psychiatric hospitals paid under the Inpatient Psychiatric Facilities Prospective Payment System, inpatient rehabilitation facilities, long-term care hospitals, cancer hospitals and children's hospitals are not eligible to participate. Eligible claims are those that were denied by a Medicare Contractor on the basis that services may have been reasonable and necessary, but treatment on an inpatient basis was not. Claims need to be under appeal or within the administrative timeframe to request an appeal review. Dates of admission must be prior to October 1, 2013. Eligible claims cannot be for items/services provided to a Medicare Part C enrollee and cannot be claims for which a hospital has already received Part B payments. Details of the claims settlement submission process can be found on the CMS website at www.cms.gov.

For more information, contact:

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com

Interested Parties Divided Over Proposed Changes to Face-to-Face Encounter Documentation

As reported in our August *Health Law Update*, the Centers for Medicare & Medicaid Services (CMS) recently published a proposed rule regarding the Home Health Prospective Payment System, which, among other things, revises the documentation requirement for CMS's home health physician face-to-face encounter requirement. CMS accepted comments to the proposed rule until September 2, 2014.

In the proposed rule, CMS proposed to eliminate the narrative requirement of the present form of the rule providing that the physician document the date of the encounter and include a narrative explaining why the clinical findings of the encounter support the requirement for home health care. CMS now believes that the narrative requirement can be eliminated because evidence in the patient's medical record should demonstrate that the patient meets the Medicare home health eligibility requirement. The physician would still be required to certify that a face-to-face encounter occurred and was performed by the physician or a non-physician practitioner.

Several interested parties submitted comments to the proposal. The Society of Hospital Medicine, a hospitalist organization, supports the proposal to eliminate the narrative requirement but was concerned that CMS's review of the medical record would simply shift the narrative burden from the certification to the medical records. The Society instead suggests a phased in approach allowing physicians to choose which method they would like to use during that time. The American Physical Therapy Association also supports the elimination of the narrative requirement and urges CMS to work with the home health community to set forth guidance on proper documentation of physician oversight.

However, the Medicare Payment Advisory Commission opposes eliminating the narrative requirement because it believes that this would increase the risk of unnecessary or unauthorized home health care services. The Commission thinks CMS should keep the current requirement in place for another year while it considers recommendations recently made by the Office of Inspector General, including the use of a standardized form for the narrative to simplify compliance, improving outreach efforts to physicians about the face-to-face requirement, and consideration of other oversight mechanisms. The final rule should be issued later this fall.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | Idornfeld@bracheichler.com Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Medicare Supplement Insurer's Plan to Use Preferred Hospital Network Does Not Violate Anti-Kickback Statute

In a recent advisory opinion, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) concluded that a proposed arrangement under which a Medicare supplement insurer would indirectly contract with hospitals for discounts on Medicare deductibles and, in turn, share cost-savings with its policyholders through premium credits would not constitute grounds for sanctions under the federal Anti-Kickback Statute or civil monetary penalty provisions of the Social Security Act.

Under the proposed arrangement, the insurer would enter into an agreement with a preferred provider organization (PPO) which contracts with hospitals across the country, providing the insurer with discounts of up to 100% of Medicare Part A deductibles that the insurer would otherwise be responsible for under its Medigap policies. The insurer, in turn, would pass part of the associated cost-savings to policyholders in the form of \$100 credits on renewal premiums. These credits, however, would be available only to policyholders that selected network hospitals.

The OIG found the arrangement posed no more than a minimal risk of fraud and abuse because: (1) neither the discounts nor the premium credits would significantly impact Medicare payments for fixed-fee services; (2) the proposed arrangement was unlikely to affect utilization because the discounts would not directly accrue to the benefit of beneficiaries and inpatient services are, in any event, unlikely to be subject to overutilization; (3) hospital competition would not be constrained because membership in the PPO's hospital network would be open to all accredited, Medicare certified hospitals; (4) medical decision-making would not be adversely impacted because physicians would receive no remuneration, and the policyholders would be free to select out-of-network hospitals without incurring additional out-of-pocket expenses; and (5) the insurer would notify policyholders that they were free to choose any hospital without financial penalty.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com

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Pharmaceutical Manufacturers May Face Sanctions for Failure to Prevent Use of Copayment Coupons by Medicare Beneficiaries

A Special Advisory Bulletin recently issued by the U.S. Department of Health & Human Services, Office of Inspector General (OIG) warns that pharmaceutical manufacturers are not doing enough to fulfill their obligation to prevent copayment coupons from being used for drug purchases by federal health care program beneficiaries.

Pharmaceutical manufacturers offer copayment coupons—including paper coupons, electronic coupons, debit cards, and direct reimbursement—to reduce or eliminate co-pays for certain brand name drugs. To the extent these copayment coupons induce the purchase of drugs by Medicare Part D or other federal program beneficiaries, manufacturers may face liability under the Anti-Kickback Statute. Failing to take the appropriate steps to preclude the use of copayment coupons in association with drugs reimbursed by the federal government may be probative of intent to induce such prohibited purchases, potentially subjecting manufacturers to Anti-Kickback sanctions.

Notices to beneficiaries and pharmacies that coupons may not be used in federal health care programs, and claims edits to prevent copayment coupons from being processed for drugs paid for by Part D are two mechanisms by which drug companies seek to ensure compliance. However, the OIG cautions in its bulletin that manufacturers must do more to ensure that these prophylactic measures are effective for all coupon formats.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com **Riza I. Dagli** | 973.403.3103 | rdagli@bracheichler.com

STATE UPDATE

Court Rulings Signal that Providers May Be at Risk of Surrendering their Ability to Bring Reimbursement Lawsuits

Recent New Jersey federal court rulings caution that providers may lose their legal rights to recover reimbursements under the Employee Retirement Income Security Act (ERISA) and state law if they fail to strengthen current language in assignment of benefit forms. ERISA, an important weapon in the legal arsenal against insurers, permits providers to recover payments on behalf of patients or customers enrolled in most employee benefit plans. New Jersey federal judges have ruled that the assignment of benefits form functions as a key, empowering providers to sue insurers through derivative ERISA, breach of contract and business tort actions. However, in the absence of adequate assignment language, these legal remedies are inaccessible to providers.

New Jersey federal judges prescribe to a variety of standards, but to safeguard a provider's rights, assignment of benefits language should conform to the most stringent approach, which requires that an assignment explicitly *transfer all of the patient's rights and benefits* under the subject insurance plan to permit a provider to sue an insurance company on a patient's behalf. It is imperative that the assignment prohibit the patient from directly suing the insurer for the same claim.

Even with an airtight assignment of benefits form, providers may still be required to overcome the additional obstacle to recovery imposed by the presence of an "anti-assignment clause" in the underlying policy. Where an anti-assignment clause exists, a provider may demonstrate that an insurer waived its right to enforcement by implicitly or explicitly acknowledging the validity of the assignment. To defeat an anti-assignment clause, providers

should maintain records of claims processing correspondence with insurers, including "claims activity logs" memorializing the subject matter and outcomes of billing communications, denials, appeals, and phone correspondence with insurers.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Proposed Regulation Would Clarify Tax Exempt Medical Supplies and Equipment

The Division of Taxation of the New Jersey Department of the Treasury proposed new regulations which would clarify the types of drugs, medical supplies and medical equipment that are exempt from New Jersey sales and use tax. Under New Jersey law, receipts from certain drugs, medical equipment and medical supplies which are sold for human use are exempt from sales and use tax, including, without limitation, prescription drugs, overthe-counter drugs, diabetic supplies, prosthetic devices and durable medical equipment. The new regulation, if adopted, would provide clarification regarding exactly which types of drugs, medical supplies and equipment fall into the sales and use tax exempt categories.

For more information, contact:

Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com **Kevin M. Lastorino** | 973.403.3129 | klastorino@bracheichler.com

Bill Would Phase Out Ambulatory Care Facility Assessments over Five Year Period

Senate Bill 2406, introduced in the Senate on September 18, 2014, would phase out, over a five-year period, the assessment on ambulatory care facilities (ACFs). Currently, an ACF with gross receipts over \$300,000 is required to pay an annual assessment equal to 2.95% of its gross receipts to the Department of Health, up to a maximum annual assessment of \$350,000. This bill would reduce the gross receipts assessment rate by providing for the following assessment rates: 2.84% in Fiscal Year (FY) 2015; 2.13% in FY 2016; 1.42% in FY 2017; 0.71% in FY 2018; and elimination of the assessment in FY 2019. We will continue to monitor the progress of the bill.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com **Mark Manigan** | 973.403.3132 | mmanigan@bracheichler.com

Alimony Amendment Signed by Governor

New Jersey joined states across the country and amended its alimony statute with Governor Christie signing the bill into law on September 10, 2014 with the law going into effect immediately. Although the amendment made considerable changes to the prior law, of most importance is the removal of permanent alimony as an option for courts, and modifications to the requirements for decreasing or terminating alimony upon retirement, job loss or when a former spouse cohabitates with another adult.

For current alimony awards, the amendment may have little or no impact. However, the amendment applies to anyone who has an alimony award decided after the law goes into effect. The law represents a compromise for the alimony reform movement. For example, the amendment eliminates the term "permanent alimony" replacing it with "open durational alimony" which now can only be utilized in marriages lasting 20 years or more, unless

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there are exceptional circumstances. This modification tries to limit the duration of alimony awards; but is likely to lead to litigation over the meaning of open duration and whether exceptional circumstances apply. Further, in marriages lasting less than 20 years, the supported spouse may seek contribution from other assets to make up for any deficit in alimony. Professionals, whose spouses sacrificed their career, may want to consider premarital agreements to protect their assets going forward. Our family law department is representing a number of clients where these issues will be at the forefront of negotiations and trials, giving us first-hand expertise and insight into this reform and its impact.

For more information, contact:

Carl J. Soranno | 973.403.3127 | csoranno@bracheichler.com

Brach Eichler In The News

Ten Brach Eichler attorneys have been selected by their peers for inclusion in the 2015 Best Lawyers in America. John D. Fanburg (health care law), Joseph M. Gorrell (health care law), Carol Grelecki (health care law), Stuart M. Gladstone (tax law, trusts and estates), Charles X. Gormally (commercial litigation, litigation—labor and employment), Alan R. Hammer (real estate law, litigation—real estate), Brian R. Lenker (banking and finance law), Stuart L. Pachman (corporate law), Allen J. Popowitz (real estate law) and David J. Ritter (corporate law, trusts and estates).

HIPAA CORNER

Covered Entities Should Get Ready for More HIPAA Audits

More HIPAA audits are coming—it is just a question of when. Speaking at a conference in September, Linda Sanches, the Senior Advisor for Health Information Privacy of the U.S. Department of Health & Human Services, Office for Civil Rights (OCR), stated that the OCR is gearing up for its newest round of HIPAA audits. As a follow up to a pilot program in 2012, the OCR will audit around 200 covered entities randomly selected from around the country and of different provider types. Ms. Sanches did not announce when the audits will begin.

Ms. Sanches advised that to prepare for an audit providers should conduct a comprehensive risk analysis. Although costly and time consuming, Ms. Sanches explained that if providers do not perform a periodic risk analysis, they will not know where they stand. Further, Ms. Sanches noted that in determining whether to audit a provider or investigate a reported breach, the OCR looks for patterns which suggest that the provider is not in compliance or does not have proper procedures in place, such as having several similar breaches. Providers that fail to have the proper procedures in place could be at risk for an audit and ultimately large settlement fines.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | Idornfeld@bracheichler.com

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Health Care Practice Group | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

Members

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com

Lani M. Dornfeld | 973.403.3136 | Idornfeld@bracheichler.com

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

Kevin M. Lastorino | 973.403.3129 | klastorino@bracheichler.com

Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com

Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

Richard B. Robins | 973.403.3147 | rrobins@bracheichler.com

Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com Jordan T. Cohen | 973.403.3144 | jcohen@bracheichler.com Michele L. Gipp | 973.403.3124 | mgipp@bracheichler.com Lauren D. Goldberg | 973.364.5228 | lgoldberg@bracheichler.com Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com Rita M. Jennings | 973.364.5204 | rjennings@bracheichler.com

Justin C. Linder | 973.403.3106 | jlinder@bracheichler.com

Conor F. Murphy | 973.364.5214 | cmurphy@bracheichler.com

Jared E. Ripp | 973.403.3148 | jripp@bracheichler.com

Peter Valenzano | 973.403.3135 | pvalenzano@bracheichler.com

Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

You have the option of receiving your **Health Law Updates** via e-mail if you prefer, or you may continue to receive them in hard copy. If you would like to receive them electronically, please provide your e-mail address to llynch@bracheichler.com. Thank you.