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## CLIENT NEWSLETTER

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### **CMS 2009 IPPS Proposed Rule: Changes Proposed to Stark Law, EMTALA and Hospital- Acquired Conditions**

The Centers for Medicare and Medicaid Services (“CMS”) recently issued its Hospital Inpatient Prospective System (“IPPS”) Proposed Rule for Fiscal Year 2009 (the “Proposed Rule”). The Proposed Rule sets forth significant changes to the Emergency Medical Treatment and Labor Act (“EMTALA”), the Stark Law, and the CMS position on payment for hospital-acquired conditions (“HACs”). The following is an overview of these proposed changes.

#### **EMTALA**

EMTALA requires a hospital to provide an appropriate medical screening, within the capability of the hospital’s emergency department, to any person who comes to a hospital emergency department and requests treatment for a medical condition. If the screening reveals an emergency medical condition, the hospital must stabilize the patient or effect an appropriate transfer to another medical facility.

In the Proposed Rule, CMS proposes to revise EMTALA such that when an individual is admitted to a hospital as an inpatient and remains unstable with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept the transfer of that individual, assuming that the transfer is appropriate and the receiving hospital has the capacity to treat the individual. Currently, EMTALA does not apply to inpatients. Therefore, presently if a hospital calls another hospital to request the transfer of an unstable inpatient with an emergency medical condition, the receiving hospital has no obligation under EMTALA to accept the transfer.

The Proposed Rule also states that as part of a hospital's obligation to have an on-call list, it may choose to participate in a "community call plan". Each hospital participating in the community call plan must have written policies and procedures in place to respond to situations in which the on-call physician is unable to respond due to situations beyond his/her control. The formal plan must be signed by all the participating hospitals and must stipulate details of each individual hospital's responsibilities.

### **STARK LAW**

The Stark Law (42 U.S.C.A. § 1395nn) precludes a provider from referring Medicare/Medicaid beneficiaries for designated health services to entities with which they, or members of their immediate family, have a direct or indirect financial relationship. As part of the Stark II Phase III Final Regulations which were issued last year, CMS introduced a rule that a physician would be deemed to "stand in the shoes" of his/her group practice or physician organization and have a direct compensation arrangement with an entity providing designated health services that contracts with his/her group. Based upon complaints of the disruptive nature of the "stand in the shoes" provision, CMS issued a notice on November 15, 2007, delaying for one (1) year the application of this provision to academic medical centers and tax-exempt integrated systems. This delay was viewed as providing CMS an opportunity to develop a permanent solution to the "stand in the shoes" provision.

The Proposed Rule sets forth three (3) proposed solutions by CMS to the "stand in the shoes" provision. Pursuant to the first solution, the "stand in the shoes" provision would not apply to a physician if the total compensation from his/her physician organization either (a) fits within the employment, personal services arrangement, or fair market value exceptions; (b) the compensation arrangement meets the academic medical center exception; or (c) the compensation arrangement is between a physician organization and a component of an academic medical center through a written agreement necessary to satisfy the academic medical center's obligations under the Medicare Graduate Medical Education rules. The second solution limits the application of the "stand in the shoes" provision to those physicians who hold an equity interest in their physician organization. The third proposed solution to the "stand in the shoes" provision would involve the development of a new exception for mission support and similar payment arrangements among physicians, physician organizations and other related designated health service providers.

It should be noted that CMS appears to be leaning toward utilizing the first solution to the "stand in the shoes" provision.

### **HOSPITAL ACQUIRED CONDITIONS**

Last year, CMS announced that beginning on October 1, 2008, it will not provide higher reimbursement payments for eight (8) events if they occur while a patient is under the care of a hospital. CMS is now proposing to expand this list to include nine (9) additional conditions. The list below sets forth the original eight (8) conditions and the proposed nine (9) new conditions for which Medicare will not provide a higher rate of reimbursement.

### **Original 8 Conditions**

- Object inadvertently left in after surgery
- Air embolism
- Blood incompatibility
- Catheter associated urinary tract infection
- Pressure ulcer (decubitus ulcer)
- Vascular catheter associated infection
- Surgical site infection – Mediastinitis (infection in the chest) after coronary artery bypass graft surgery
- Certain types of falls and trauma

### **Proposed Additional 9 Conditions**

- Surgical site infections following certain elective procedures
- Legionnaires' disease (type of pneumonia caused by a specific bacterium)
- Extreme blood sugar derangement
- Iatrogenic pneumothorax (collapse of the lung)
- Delirium
- Ventilator-associated pneumonia
- Deep vein thrombosis / Pulmonary Embolism (formation/movement of a blood clot)
- *Staphylococcus aureus* septicemia (bloodstream infection)
- *Clostridium difficile* associated disease (bacterium that causes severe diarrhea and more serious intestinal conditions such as colitis)

A second initiative CMS proposes under the Proposed Rule is an expansion of the hospital quality measure reporting program. With this program, Medicare again uses reimbursement as leverage, decreasing payment amounts if a hospital fails to participate in the voluntary reporting of standardized quality measures. In order to qualify for a full update to their FY 2009 payment rates, hospitals are currently required to report on 30 quality measures on their claims for Medicare inpatient services. The new proposed policy on quality measure reporting would add an additional 43 measures on which to report, bringing the full list to 73 for FY 2010. This proposed rule would apply to more than 3,500 acute care hospitals paid under the IPPS and a final rule would implement the following additions for quality measurements:

- Hospital readmissions – 3 new measures
- Venous thromboembolism measures (VTEs) – 6
- Stroke measures – 5
- Nursing Care – 4
- Cardiac surgery measures – 15
- Surgical Care Improvement Project (SCIP) – 1
- Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ) – 5
- Inpatient Quality Indicators developed by the AHRQ – 4

CMS is accepting comments on the Proposed Rule through June 13<sup>th</sup>. It is expected that the Final Rule will be published by August 1<sup>st</sup> and the policies and payment rates set forth within the Proposed Rule will become effective on October 1<sup>st</sup> of this year.

## Final Regulations Issued for IRS Intermediate Tax Sanctions

The United States Internal Revenue Service (“IRS”) recently released Final Intermediate Tax Sanctions Regulations (the “Final Regulations”) for those tax-exempt entities which engage in an excess benefit transaction. The Final Regulations confirm the basis for revocation of an entity’s tax-exempt status and also provide guidance on measures that tax-exempt entities should utilize to reduce the risk of revocation as a result of an excess benefit transaction.

Section 4958 of the United States Internal Revenue Code (“IRC”) provides for the imposition of intermediate tax sanctions in the event of an “excess benefit transaction” between an “applicable tax-exempt organization” and a “disqualified person”. (The sanctions are considered “intermediate” because they are at a mid-point between the IRS maintaining a neutral position toward the inurement and in the alternative, completely revoking the organization’s tax-exempt status.) An excess benefit transaction is a transaction in which any economic benefit is provided by an applicable tax-exempt organization to a disqualified person, if the value of the economic benefit provided exceeds the value of the consideration derived for providing the benefit. Applicable tax-exempt organizations are any organizations described in Section 501(c)(3) or (c)(4) of the IRC. A disqualified person includes: (1) board members; (2) Presidents, Chief Executive Officers or Chief Operating Officers; (3) Treasurers and Chief Financial Officers; and (4) other individuals who have a substantial influence over the affairs of the organization.

By way of additional background, it is important to point out that an excess benefit transaction, such as a compensation arrangement, is entitled to a “rebuttable presumption of reasonableness” if: (1) the compensation arrangement was approved in advance by an authorized body (governing body) of the applicable tax-exempt organization, composed entirely of individuals who do not have a conflict of interest with respect to the arrangement; (2) the authorized body obtained and relied upon appropriate data as to comparability prior to making its determination; **and** (3) the authorized body adequately documented the basis for its determination concurrently with making that determination.

The Final Regulations set forth guidance on certain factors the IRS will consider in determining whether to revoke an organization’s tax-exempt status (instead of just levying an intermediate tax) when that organization has engaged in one or more excess benefit transactions. These factors include the following:

1. The size and scope of the organization’s regular and ongoing exempt activities;
2. The relationship between the size and scope of the excess benefit transaction(s) and the organization’s regular exempt activities;
3. Whether the organization has a history of engaging in excess benefit transactions;
4. Whether the organization has adopted compliance safeguards intended to prevent the occurrence of future excess benefit transactions; and

5. Whether the excess benefit transaction has been corrected (or the organization has made a good faith effort to seek correction).

The Final Regulations set forth six (6) examples to illustrate the application of the above factors to specific circumstances. The example that has received perhaps the most notable attention since the release of the Final Regulations is “Example Six”, which addresses an executive compensation scenario. In the example, the offending entity is a large organization with substantial assets and revenues. The entity furthers its exempt purposes by providing social services to the population of a specific geographic area. The entity’s Board of Directors adopted written procedures for setting executive compensation and appointed a Compensation Committee to gather data on compensation levels paid by similarly situated organizations for functionally comparable positions. On the basis of the Compensation Committee’s recommendations, the Board approved new compensation packages for the entity’s top executives. During a subsequent examination, the IRS found that the Compensation Committee relied exclusively on compensation data from organizations that perform similar social services to the entity. The IRS concluded, however, that the organizations used in the data were not similarly situated because they served substantially larger geographic regions with more diverse populations and were larger than the entity in terms of annual revenues, total operating budget, number of employees, and number of beneficiaries served. The IRS concluded that the Compensation Committee did not rely on “appropriate data as to comparability” within the meaning of the regulations. Therefore, the entity would not be able to meet the “rebuttable presumption of reasonableness.” As a result, the entity’s Board reconstituted the Compensation Committee to include members with relevant experience, amended Compensation Committee procedures, reconsidered the comparability data, and renegotiated the compensation arrangements based upon new data. The example is important insofar as it demonstrates that although an entity may appear to take the necessary steps to meet the rebuttable presumption of reasonableness under the Intermediate Tax Sanctions, it must ensure that it relies on appropriate data as to comparability – specifically relying upon comparability data of organizations that are “similarly situated”.

If you have any questions regarding the Final Regulations or any part of the Intermediate Tax Sanctions, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

## **Massachusetts DPH Proposes Amendments to Determination of Need Regulations**

The Massachusetts Department of Public Health (“DPH”) recently issued proposed Amendments to the Determination of Need (“DoN”) regulations, 105 C.M.R. 100.000 *et seq.* (the “Amendments”), making a number of substantive changes and clarifying certain existing DPH policies. In addition to changes that update or delete outdated references, the Amendments enable DPH to consider duplication of services with the addition of hospital beds at new locations. The Amendments also end a grandfathering provision in the statute that has enabled the acquisition of new technology (e.g., MRI, PET, and Radiation Therapy) through the purchase of so-called physician exemption letters. The Amendments also enable staff to add conditions to approvals that are granted outside of the normal DoN process (“308 exemptions”), which will result in the imposition of community benefits requirements on projects that were formerly free of such requirements.

DPH has expressed concern regarding the recent trend of expansion of outpatient services of major teaching hospitals into suburban communities, such as Brigham and Women's Hospital in Chestnut Hill, Beth Israel Deaconess Medical Center in Lexington, and Massachusetts General Hospital in Danvers. Although these outpatient services are by statute exempt from DoN review, there is a growing concern that the parent hospitals might add inpatient beds at these satellite locations and compete with local community hospital providers. The Amendments, which require the filing of a DoN application in order to add beds at a satellite location, address this concern. Under this requirement, applicants would need to demonstrate that the proposed addition of beds does not duplicate the services of any existing community hospital provider. DPH has also proposed an Amendment that identifies non-duplication of services as a DoN factor in its own right.

Prior to 1991, health facilities – but not physicians – needed determinations of need to acquire MRI technology. Similarly, prior to 1993, health facilities – but not physicians – needed determinations of need to acquire PET scanning and radiation therapy technology. A series of amendments to the DoN statute in 1991 and 1993 brought first MRI technology in 1991 and then the other new technologies in 1993 into the purview of DoN, whether or not the technologies were to be physician owned. However, the legislation that created this “level playing field” also grandfathered those physicians who filed “notices of intent to acquire” PET scanning and radiation therapy technology by certain dates, in 1991 and 1993, and these letters remain in existence and remain viable. DPH has expressed concern regarding these letters because they allow the acquisition of new technology outside the purview of DoN and add to the costs of healthcare. The Amendments propose to sunset the letters, so that any letter that has not been implemented by the sunset date will be voided.

Section 308 of the DoN regulations authorizes the program director to grant approvals outside of the normal DoN process. This section is used to enable hospitals to acquire their own MRI capacity when, as a result of historical circumstances, the MRI services were obtained through a vendor who is the holder of a DoN for the service. Currently this section permits the program director to add a condition to such approval. The Amendments state that a community benefits condition is permissible in these circumstances. Additionally, section 308 currently requires the applicant to file a complete DoN application. In some cases, these applications are never reviewed. In order to reduce the burden on recipients of such approval the Amendments will require the filing of a full DoN application only upon the order of the program director.

The Amendments also seek to clarify certain DPH policies. The Amendments would provide that the build-out of shell space is a significant change to a project. They would also require a party to seek a determination from DPH as to whether a project in its entirety would require a DoN where a party builds out shell space associated with a project that did not require a DoN because it was below the expenditure minimum. Finally, consistent with proposed changes to the regulations governing substance abuse programs and facilities, DPH has proposed to remove references to DoN review for such projects.

DPH will hold a public hearing on the proposed amendments on May 20, 2008. A copy of the proposed amendments and related materials may be accessed at:  
[http://www.mass.gov/Eeohhs2/docs/dph/legal/don\\_propose\\_amend\\_20080409.doc](http://www.mass.gov/Eeohhs2/docs/dph/legal/don_propose_amend_20080409.doc).

## CMS Issues Final E-Prescribing Rule

The Centers for Medicare and Medicaid Services recently issued its final rule for electronic prescribing (“e-prescribing”) (the “Final Rule”). The Medicare Modernization Act of 2003 directed the Secretary of the United States Health and Human Services to establish regulations that would permit certain arrangements to foster the adoption of e-prescribing technology. Although the use of e-prescribing would be optional for physicians and pharmacies, the Medicare Modernization Act required drug plans participating in the new Medicare Part D prescription drug benefit to support e-prescribing. As a result, on November 7, 2005, CMS published “foundation standards” that became effective on January 1, 2006. While using these foundation standards as a basis for e-prescribing, further research was done to evaluate other potential standards and protections which have now been announced as part of the Final Rule. These new standards are essentially electronic tools for use in e-prescribing. They include the following:

- *Formulary and benefits*: allows doctors and other prescribers to communicate with Part D sponsors about which drugs are covered by a Medicare eligible individual’s prescription drug benefit plan.
- *Medication history*: allows doctors and other providers, as well as dispensers and Part D sponsors, to communicate among themselves about prescribed medications a beneficiary has taken or is taking, including those prescribed by other providers.
- *Fill status notification*: allows doctors and other providers to receive an email notice from a pharmacy or other dispenser with information regarding patients’ prescriptions (including whether the prescription has been picked up or is partially filled).

The Final Rule also adopts the National Provider Identifier (“NPI”) for e-prescribing under Medicare Part D. Consequently, providers, dispensers, and Part D sponsors who utilize e-prescribing will need to use the NPI to identify individual healthcare providers in Part D e-prescribing transactions.

The new standards apply to all Part D sponsors, prescribers, and dispensers that electronically transmit prescriptions and prescription related information about Part D covered drugs prescribed for Part D eligible patients. Although use of the e-prescribing system is voluntary, those who do use it must comply with these new standards. The final rule will take effect on April 1, 2009.

## IRS Refines Position on Corporate Governance

The United States Internal Revenue Service (“IRS”) recently updated its position paper concerning the governance of tax-exempt, non-profit organizations. The position paper, entitled “*Governance and Related Topics – 501(c)(3) Organizations*” (the “Position Paper”) addresses what the IRS believes to be the policies and practices of a well-governed charity through six (6) different topics, including: mission; organizational documents; governing body; governance and

management policies; financial statements and Form 990 reporting; and transparency and accountability. The following is an overview of the policies and practices set forth for consideration by the IRS within these topics:

**1. Mission**

The IRS encourages charities to establish and regularly review the organization's mission. The Position Paper states that a clearly articulated mission, adopted by the Board of Directors, serves to explain and popularize a charity's purpose and guide its work.

**2. Organizational Documents**

The Position Paper emphasizes the importance of a charity maintaining organizational documents that provide a framework for its governance and management.

**3. Governing Body**

The IRS encourages an "active and engaged board" believing that such a board is important to the success of a charity and to its compliance with applicable tax law requirements. The Position Paper notes that successful governing boards include individuals who are not only knowledgeable and engaged, but selected with the organization's needs in mind (e.g. accounting, finance, compensation and ethics). The IRS states that it reviews board compensation of charities to determine whether the board represents a broad public interest, and to identify the potential for insider transactions which could result in misuse of charitable assets. The Position Paper encourages charities with local chapters, branches or affiliates to have procedures and policies in place to ensure that the activities and operations of such a Board are consistent with the parent organization.

**4. Governance and Management Policies**

The Position Paper points out that although the Internal Revenue Code does not require charities to have governance and management policies, the IRS nevertheless encourages charities to have policies relating to executive compensation, conflicts of interest, investments, fundraising, documenting governance decisions, document retention and destruction, and whistleblower claims. Of particular note, the IRS encourages governing bodies and authorized sub-committees to take steps to ensure that minutes of their meetings and actions taken by written action or outside of meetings, are contemporaneously documented.

**5. Financial Statements and Form 990 Reporting**

The Position Paper states that the board, either directly or through a board-authorized committee, should ensure that financial resources are used to further charitable purposes and that the organization's funds are appropriately accounted for by regularly receiving and reviewing up-to-date financial statements and any auditors letters or finance and audit committee reports. Although the IRS has not taken an official position, it does note within the Position Paper that many charities provide copies of the IRS Form 990 to its governing body and other internal governance or management officials, either prior to (preferably) or after it is filed with the IRS.

## 6. Transparency and Accountability

The Position Paper notes that by providing full and accurate information about its mission, activities, finance and governance publicly available, a charity encourages transparency and accountability to its constituents.

The Position Paper is an important document for charities. Organizations should consider providing a copy of the Position Paper to the members of its governing board. The Position Paper can be accessed at: [http://www.irs.gov/pub/irs-tege/governance\\_practices.pdf](http://www.irs.gov/pub/irs-tege/governance_practices.pdf). If you have any questions or concerns with respect to the Position Paper, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

## OIG Amends Self-Disclosure Protocol

On April 15, 2008, the United States Office of Inspector General (“OIG”) of the U.S. Department of Health and Human Services, posted on its website an open letter to all health care providers setting forth revisions to its Self-Disclosure Protocol (“SDP”). The SDP was created by the OIG in 1998 as a means of protecting the integrity of federal health care programs (e.g., Medicare, Medicaid, etc.) by encouraging providers to voluntarily disclose self-discovered evidence of potential fraud.

The purpose of the new revisions to the SDP is to help make the idea of voluntary self-disclosure more attractive to providers. Specifically, the open letter from the OIG states that providers who disclose in good faith, fully cooperate with the OIG and provide requested information in a timely manner will generally not be required to enter into Corporate Integrity or Certification of Compliance Agreements with the OIG. However, the open letter states that in addition to the information already required under the initial disclosure of the SDP, the following information must also be disclosed:

1. A complete description of the conduct being disclosed;
2. A description of the provider’s internal investigation or a commitment regarding when it will be completed;
3. An estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and
4. A statement of the law potentially violated by the conduct.

Furthermore, the open letter states that a provider must now be in a position to complete its investigation and damages assessment within three (3) months after acceptance into the SDP.

The prospect of not having to enter into a Corporate Integrity or Certification of Compliance Agreement is indeed an incentive for providers to participate in the SDP. Nevertheless, providers should consult with their compliance officer and counsel before seeking to participate in the SDP. The attorneys at The Rogers Law Firm are available if you have any questions regarding the SDP.

## First Circuit Rules EMTALA Covers Patient in Ambulance En Route to Hospital

The United States Court of Appeals for the First Circuit (the “First Circuit”) recently issued a decision in the matter of *Morales v. Sociedad Espanola de Auxilio Mutuo y Beneficiencia*, No. 07-1951 (1<sup>st</sup> Cir., Apr. 18, 2008), holding that the Emergency Medical Treatment and Labor Act (“EMTALA”) applies where a woman suffering from symptoms of an ectopic pregnancy was in an ambulance on its way to a hospital and the hospital’s Emergency Department was notified of her imminent arrival. The decision represents a significant split from the position of the Centers for Medicare and Medicaid Services (“CMS”) with respect to the applicability of EMTALA.

The First Circuit’s decision in *Morales* involved a Puerto Rico hospital emergency department’s refusal to treat an uninsured patient who was being transported to that site in an ambulance. Plaintiff Carolina Morales was at work when she began experiencing severe abdominal pains. An ambulance was called to take her to the hospital. Ms. Morales informed the paramedics that her obstetrician had diagnosed her with a possible ectopic pregnancy two (2) days earlier. The ambulance proceeded to Hospital Espanol Auxilio Mutuo de Puerto Rico (the “Hospital”) where Ms. Morales’ obstetrician regularly practiced. The ambulance was not owned by the Hospital and its paramedics were not hospital employees. In transit to the Hospital, the paramedics called ahead to the Emergency Department and notified Dr. Salvatore Marquez, the Department’s Director, of Ms. Morales’ condition and her imminent arrival. Dr. Marquez informed the paramedics that he was very busy and asked them to call back with more information about the patient. When the paramedics called back, Dr. Marquez allegedly asked whether Ms. Morales had health insurance coverage. “Receiving no such assurances, Dr. Marquez abruptly terminated the call (an action that the paramedics interpreted as a refusal to treat Ms. Morales at the Hospital’s Emergency Department).” The paramedics then took Ms. Morales to another hospital.

Ms. Morales brought suit against the Hospital and several individual defendants in the U.S. District Court for the District of Puerto Rico, alleging EMTALA violations and common law tort claims. The Hospital moved for a summary judgment on the EMTALA claim arguing that EMTALA is not triggered until the patient arrives on its premises. Pursuant to EMTALA (42 U.S.C., § 1395dd(a)), “if any individual . . . comes to the Emergency Department [of a covered hospital] and a request is made on the individual’s behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening and examination.” The EMTALA regulations further state that “an individual in a non-hospital-owned ambulance off hospital property is not considered to have come to the hospital’s Emergency Department, even if a member of the ambulance staff contacts the hospital . . . and informs the hospital that they want to transport the individual to the hospital for examination and treatment.” (42 C.F.R. § 489.24(b)(4)) The District Court granted the Hospital’s Motion for a Summary Judgment and dismissed the supplemental common law tort claims without prejudice. Ms. Morales appealed to the First Circuit.

In its decision reversing the District Court’s granting of Summary Judgment, the First Circuit held that “the statute and its implementing regulations must be interpreted in a way that prevents hospitals from ‘dumping’ patients. An interpretation of the statute concluding that an individual en route to the Hospital, under the plaintiff’s version of the facts, has ‘come to’ the Emergency Department . . . comports with EMTALA’s primary goal and hinders efforts to turn away prospective patients because of their economic status.” The First Circuit further held that “if a hospital was allowed to turn away an individual while she was en route to the hospital under

these facts, an uninsured or financially strapped person could be bounced around like a ping-pong ball in search of a willing provider” contrary to EMTALA’s primary goal.

The decision by the First Circuit is significant not only because of the substance of the ruling, but also because the First Circuit is the appellate court for cases filed in the U.S. District Court for the District of Massachusetts. Therefore, the decision in *Morales* serves as binding precedent for cases filed in the U.S. District Court for the District of Massachusetts. Furthermore, the decision also serves as non-binding precedent for civil actions filed in the state courts for the Commonwealth of Massachusetts. It should be noted, however, that the First Circuit’s decision in *Morales* does not preclude a hospital from not accepting a patient when it is on diversion status. Rather, the First Circuit’s decision seeks to prevent a situation where a hospital, in non-diversion status, rejects a patient en route to the hospital based upon what appears to be their financial ability to cover the cost of any treatment to be provided. Hospitals should review their EMTALA policy to ensure that it complies with the *Morales* decision

If you have any questions or concerns with respect to the First Circuit’s decision in *Morales*, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

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