Summary of CY 2024 Proposed Rule for Medicare Advantage Organizations and Part D Sponsors

On December 27, 2022, the Centers for Medicare & Medicaid Services (CMS) published in the federal register the Contract Year 2024 Policy Proposed Rule for Medicare Advantage (MA) organizations and Part D sponsors (the "Proposed Rule"). The Proposed Rule makes several changes to Medicare Advantage and Part D regulations, including new requirements for prior authorization, marketing and communications, behavioral health network adequacy, star ratings, health equity, medication therapy management, and more. The table on the pages below highlights significant changes in the Proposed Rule, including their potential impacts on MA organizations and Part D plan sponsors ("MAOs"), and identifies out subject areas where CMS has solicited feedback from MAOs or where MAOs may want to provide comments. Comments are due February 13, 2023.

Major Provisions of the Proposed Rule

- MA and Part D Prescription Drug Plan Quality Rating System (Star Ratings)
- Medication Therapy Management (MTM) Program
- Strengthening Translation and Accessible Format Requirements for MA, Part D, and D-SNP Enrollee Marketing and Communication Materials
- Health Equity in MA
- Utilization Management (UM) Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of UM Tools
- MA and Part D Marketing
- Behavioral Health in MA
- Enrollee Notification Requirements for MA Provider Contract Terminations
- Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries through the Limited Income Newly Eligible Transition (LI NET) Program
- Changes to an Approved Part D Formulary – Immediate Substitutions
- Expanding Eligibility for Low-Income Subsidies (LIS) Under Part D of the Medicare Program

Proposal[i]	Impact on MAOs	Feedback Solicited by CMS/ Potential Comments
Prior Authorization §§ 422.101, 422.112, 422.137, 422.138, 422.202		
CMS Concern: CMS noted that commenters expressed concern about delays resulting from prior authorization. Various stakeholders (including provider groups, patient advocacy organizations, and other advocacy groups) have expressed concerns over the quality of MAO decision-making procedures as they apply to prior authorization. An April 2022 OIG Report concluded that MA plans denied prior authorization requests even when services met Medicare coverage guidelines. OIG also concluded that some requests were inappropriately denied due to MA plan errors.		
Purpose: The Proposed Rule, which limits the contexts in which MAOs may require prior authorization, seeks to ensure timely access to medically necessary care for beneficiaries. In particular, CMS seeks to ensure that prior authorization does not cause MA beneficiaries to receive delayed or inconsistent care in relation to Original Medicare beneficiaries.		
- MAOs will be prohibited from denying coverage based on criteria not found in Original Medicare coverage policies. In the absence of relevant Original Medicare coverage policies, MAOs will be permitted to create organizational coverage policies, though they must be based on clinical literature or common treatment guidelines. The evidence backing up an internal coverage policy decision, along with a explanation detailing how the evidence supports the coverage criteria, must be made available to CMS and the public. - Plans will be required to provide a minimum 90-day transition period for beneficiaries switching MA plans, during which the beneficiary can receive treatment authorized under the previous plan, even if the treatment is subject to prior authorization under the new plan. A beneficiary switching plans could use the 90-day transition period to obtain prior authorization under the new plan. - MAOs will be required to establish a Utilization Management ("UM") Committee to conduct an annual review to ensure that the MAO's prior authorization policies are consistent with	- MAOs will need to review and update policies and procedures regarding UM and PA to comply with new requirements -Policy review should include reference to all applicable Original Medicare coverage criteria - Establishment of UM Committee (similar to P&T committee) meeting CMS requirements to review all UM policies - Limitations on UM tools may undermine ability to coordinate care and manage costs	- Role of MAO's internal coverage criteria in addition to existing requirements - Definition of treatment guidelines and clinical literature that would justify internal coverage criteria used in absence of NCDs, LCDs, or Original Medicare rules - Role of medical director in ensuring clinical accuracy of medical necessity determinations - Alternative timeframes for which PA should be required to be valid without re-review - Burden of implementing proposed requirements, including impact on care

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Original Medicare coverage rules. The UM Committee would be led by the MAO's medical director, and the majority of members would be practicing physicians from various specialties. Among these physicians, at least one is required to be free of conflict relative to the MAO and at least one must be an expert in care for elderly or disabled individuals.		coordination, reducing inappropriate utilization, and promoting cost-efficient care - Scope and composition of UM Committee, including role of providers in development of UM policies/procedures
Expanding Medication Therapy Management (MTM) Eligibility § 423.153		
CMS Concern: Under the current rule, Part D sponsors are subject to flexible requirements when establishing their MTM eligibility criteria. CMS is concerned about decreasing MTM eligibility rates and Part D sponsors tendency to use the most restrictive criteria currently permitted.		
Purpose: The purpose of MTM generally is to better manage care for beneficiaries with certain medical conditions with complex medication needs and avoiding adverse events and drug interactions. This portion of the Proposed Rule seeks to ensure that more of these beneficiaries' medication needs are being met, particularly beneficiaries with the core chronic conditions the Proposed Rule identifies. CMS sees the flexibility of MTM eligibility criteria as allowing plans to minimize coverage for individuals who might benefit from an MTM program. The changes will raise the floor of the required eligibility criteria to counteract plans' incentive to target fewer beneficiaries for MTM coverage.		
- CMS will codify 9 "core chronic conditions" that plans must target for MTM eligibility. MAOs are required to include the core chronic conditions in their MTM targeting criteria. - CMS will add HIV/AIDS to the list of core chronic conditions, for a total ten conditions that MAOs are required to target for MTM eligibility. - CMS will lower the maximum number of prescribed drugs a sponsor may require for MTM eligibility from 8 to 5. Currently, plan sponsors can require beneficiaries to be taking at least 8 drugs to become eligible for their MTM program. CMS proposes to lower the amount of drugs to 5, so that plan	- Part D sponsors, including MAOs and standalone Part D plans, will need to adjust their MTM eligibility criteria to reflect the new standards, including incorporating the 9 core chronic conditions and the lower maximum number of drugs that may be required into the criteria. -Sponsors will need to evaluate their staffing and other resources	- Future rulemaking to expand the MTM program - Whether CMS should consider adding additional diseases, especially cancers, to the 9 core chronic conditions - Whether MTM services furnished under a Part D MTM program are an effective mechanism for management of certain diseases

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sponsors cannot require beneficiaries to be taking more than 5 drugs to trigger MTM eligibility. - CMS proposes to revise the methodology for calculating the cost threshold for MTM eligibility. Specifically, CMS is lowering the cost threshold to match the average annual cost of 5 generic drugs.	for MTM, anticipating larger program participation with the new targeting criteria.	
MA and Part D Marketing Subpart V of Parts 422 and 423		
CMS Concern: CMS is very concerned about third-party marketing practices, including the proliferation of marketing materials that generically promote enrollment in MA plans but do not mention a specific plan name. CMS expressed concern about organizations that publicize and distribute "copycat" marketing materials that mislead the reader into thinking that the organization is Medicare or the Federal Government. CMS mentions storefronts with "Medicare" in a large font with miniscule disclaimers, postcards mimicking Medicare enrollment forms, and logos strongly resembling the HHS logo. The new marketing regulations focus on the Medicare name (and the names of related organizations, such as HHS). CMS expresses that this focus is necessary because of the danger that the public will be misled into believing that the organizations at issue are Federal Government organizations.		
Purpose: These new proposed regulations seek to protect Medicare beneficiaries from confusing and potentially misleading marketing and ensure that they have accurate and necessary information to make coverage choices that meet their needs. CMS already prohibits misleading marketing, but the proposed regulations focus on specific tactics that CMS believes are especially common or problematic.		
- MAOs will be required to notify enrollees annually in writing of the ability to opt out of phone calls regarding MA and Part D plan business. - Agents will be required to explain the effect of an enrollee's enrollment choice on their current coverage. - MAOs and agents will be prohibited from marketing of benefits in a service area where those benefits are not available – MAOs and agents will be prohibited from marketing of savings based on comparisons of typical expenses incurred by uninsured individuals, unpaid costs of dually eligible	Proposals would dramatically alter the ways that agents and brokers can market and sell Medicare plans - CMS would enforce the agent restrictions through its relationship with MAOs, holding MAOs responsible for agent non-compliance - MAOs will need to adjust agent training policies and procedures to	- Whether the proposed regulatory changes will sufficiently achieve the goals CMS outlined of protecting beneficiaries - Recommend removal of requirement that MAOs report any agent non-compliance to CMS as overbroad

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beneficiaries, or other unrealized costs of Medicare beneficiaries. - MAOs and agents will be prohibited from use of superlatives (best, etc.) unless supported by documentation from the current or prior year. - MAOs and agents will be prohibited from running ads that do not mention the specific plan name. - MAOs and agents will be prohibited from running ads that use words and imagery (including Medicare name or logo) in a way that may confuse or mislead beneficiaries or misrepresent the plan as an Original Medicare plan or Federal Government program. - Agents may not engage in sales presentations immediately following an educational event. - Agents prohibited from distributing/collecting of scope of appointment and business reply cards at educational events. - Agents will be prohibited from conducting sales/enrollment meetings within 48 hours of receiving beneficiary consent for such a meeting. - MAOs must report to CMS any agents that fail to adhere to CMS requirements. - TPMOs will be required to disclose to beneficiaries all of the plans the TPMO sells. - Agents will be required to use a standardized list of questions before enrolling an individual. Agent must also provide a standardized pre-enrollment checklist to prospective enrollees. The standardized list of questions and checklist are intended to identify specific enrollee needs as they relate to MA plan coverage.	reflect the new marketing restrictions - Implementation of proposed requirements will take a substantial communications effort to educate agents and brokers -MAOs should bolster agent oversight processes to ensure compliance - MAOs will need to review marketing materials to reflect the new restrictions -MAOs will need to adjust policies for marketing materials to fit the restrictions - Recommend updated compliance review checklists for Medicare marketing materials	

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Behavioral Health Network Adequacy §§ 422.112, 422.116		
CMS Concern: CMS seeks to address stakeholder comments pointing out that current network adequacy requirements under-prioritize behavioral health. The Proposed Rule intends to address challenges in building MA behavioral health networks and improve access to behavioral health services for beneficiaries. The proposed behavioral health requirements are similar to network adequacy requirements for other specialties, including wait time requirements resembling those for primary care services and the potential for behavioral health emergency care services. The new requirements imply a CMS position that behavior health specialties should not be categorized within MA as inferior to or less essential than other healthcare, while also seeking to address the opioid crisis. Communicating the urgency of this change, CMS cites the increasing rate of opioid overdose deaths during the COVID-19 pandemic. The preamble explains that beneficiaries may not know how to access Medications for Opioid Use Disorder (MOUD) or may not know which types of providers offer MOUD. To that end, CMS proposes adding to provider directories whether providers offer MOUD.		
Purpose: CMS intends to strengthen network adequacy requirements and reaffirm MAOs' obligation to provide behavioral health services. This is part of a broader strategy to improve behavioral health access.		
- MAOs will be required to include Clinical Psychology Licensed Clinical Social Worker and Prescribers of Medication for Opioid Use Disorder as specialty types for evaluation as part of the network adequacy evaluation. The network adequacy evaluation includes base time and distance standards for behavioral health providers, as well as a minimum number of providers within each service area. - CMS will amend general access to services standards in 422.112 to include a requirement that a network include providers specializing in behavioral health services. - CMS will codify (from existing guidance) standards for wait times that apply to primary care and behavioral health services. - Some behavioral health services may qualify as emergency services not subject to prior authorization. - MAOs must establish programs to coordinate covered services with community and social services to behavioral health services	- MAOs will need to review their provider networks to ensure adequate behavioral health care access and identify Prescribers of Medication for Opioid Use Disorder. - Recommend contacting each provider and determining whether accepting new patients and wait times for care. - MAOs will likely need to expand their networks to include more behavioral health providers. - MAOs must establish programs to coordinated covered services	- Whether the proposed improvements to the provider directories are sufficient to protect beneficiaries who need providers with certain cultural and linguistic competencies - Recommend asking that CMS acknowledge the shortage of behavioral health providers and develop an exceptions process to new standards that takes this shortage into account

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programs to close gaps in treatment between physical and behavioral health.	with community and social services. - MAOs will need to alter provider databases to add Prescribers of Medication for Opioid Use Disorder.	
Enrollee Notification Requirements for Provider Contract Terminations § 422.111(e)		
CMS Concern: Beneficiaries are not receiving adequate notice of contract terminations for primary care and behavioral health providers. Specifically, CMS is concerned that beneficiaries are not finding out about contract terminations until they attempt to make an appointment with their primary care or behavioral health provider, and that this delay in discovering the termination is preventing them from receiving timely care.		
Purpose: CMS seeks to ensure the stability and timeliness of primary care and behavioral health treatment. The proposal is also meant to ensure that, after a provider contract termination, enrollees understand their options for either finding a new provider or continuing to see their current provider.		
- CMS will establish enrollee notification requirements for both no-cause and for-cause provider contract terminations. CMS will also add more stringent notification requirements for primary care and behavioral health provider contract terminations. Specifically, when a primary care or behavioral health provider's contract is terminated, all enrollees who are patients of that provider must be notified. - MAOs must provide notice to enrollees at least 45 calendar days before the termination effective date for contract terminations involving a primary care or behavioral health provider. This notice must be communicated both in writing and via telephone. The notification must inform the enrollee that the provider will no longer be working with the network and the contract termination effective date. It must also include	- MAOs should adjust their policies regarding enrollee notification for provider contract termination to ensure that the MAO is providing the required notices to enrollees.	-CMS solicits comment on this portion of the proposed rule but does not specify a particular element of this section of the rule for comment.

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information such as names and phone numbers of in-network providers that the enrollee may access for continued care, how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider, and the MAO's call center telephone number, TTY number, and hours and days of operation. MAOs must also provide information about the Annual Coordinated Election Period and the MA Open Enrollment Period and explain that an enrollee who is impacted by the provider termination may contact 1– 800–MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period.		
Expanding LIS to Align with Inflation Reduction Act (IRA) §§ 423.773, 423.780		
CMS Concern: CMS seeks to implement the IRA provisions intended to expand access to LIS for beneficiaries who may struggle to afford their medications. The purpose of this change is to ensure access to medication for those near the federal poverty line who might otherwise have difficulty paying for prescription drugs.		
Purpose: This portion of the Proposed Rule will improve access to affordable prescription drug coverage for low-income beneficiaries. The expanded LIS eligibility falls in line with the broader goal of advancing health equity by providing financial assistance to more beneficiaries than in previous years.		
- Full LIS eligibility will expand to include individuals with incomes up to 150% of the federal poverty level and who meet statutory resource requirements. - CMS will codify a permanent LI NET program. Currently, the LI NET program is a temporary demonstration program which provides temporary Part D coverage for low-income beneficiaries who qualify for Medicaid but do not yet have prescription drug coverage. The proposed rule would make the LI NET program permanent.	- MAOs should prepare for a larger proportion of beneficiaries in future contract years to be receiving LIS. - Implementation will require customer service training and revision of member materials regarding LIS.	-This portion of the proposed rule is an implementation of the IRA. CMS did not solicit comment on this portion of the proposed rule.

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Part D Formulary Flexibility §§ 423.4, 423.100, 423.104, 423.120, 423.128		
CMS Concern: When CMS first adopted its immediate substitution policy, it stated the policy would not apply to biologics until interchangeable biologic products became available through Part D. Currently, there is at least one set of interchangeable biologic products. Allowing immediate substitution of interchangeable products enables Part D plan sponsors to better manage high drug costs for beneficiaries. Biologics tend to be especially costly, making interchangeability of biologics especially urgent in light of rising attention within CMS on beneficiary drug costs.		
Purpose: The purpose of the new immediate substitution allowances for biologics is to expand CMS's existing immediate substitution policies for non-biologic brand name and generic drugs into biologics. This is intended to provide Part D sponsors with additional tools to manage drug costs.		
- Part D sponsors may immediately remove from the formulary certain biologic drugs and substitute them with an equivalent. CMS proposes to permit Part D sponsors to immediately substitute (1) a new interchangeable biological product for its corresponding reference product; (2) a new unbranded biological product for its corresponding brand name biological product; and (3) a new authorized generic for its corresponding brand name equivalent.	- Part D sponsors will be permitted to immediately remove from the formulary certain biologic drugs and substitute them with an equivalent. - Pharmacy departments should be prepared to monitor approval of equivalents and have processes in place to make prompt formulary changes with appropriate communications to providers and beneficiaries. - Recommend proactive communications with PBM and/or pharmacy network regarding policy change.	- CMS does not solicit comment regarding this portion of the proposed rule.

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[ii]**Strengthening Translation Requirements** §§ 422.2267, 423.2267		
CMS Concern: The proposed translation requirements are intended to address accessibility of materials for beneficiaries who do not speak English or are otherwise prevented from reading English-language materials. CMS expressed concern that individuals who cannot read English-language materials might face significant barriers when navigating the already complex D-SNP system. CMS indicated that this is especially concerning in cases when inability to read English-language materials coincides with social risk factors for health. In particular, the expanded cultural competency requirements, and the requirement that provider databases list linguistic and cultural competencies, are intended to decrease the extent to which those adversely affected by inequality or poverty face additional barriers to quality health care.		
Purpose: This portion of the Proposed Rule seeks to ensure that individuals who cannot read English-language materials have access to comparable materials to those who can read English. It extends current MAO translation and accessibility requirements to D-SNPs. It also seeks to ensure that those who cannot read English but can read another language common to a plan's service area, can access materials on a standing basis in the language they speak. The translation requirements apply not only to those who primarily speak a language besides English, but also to beneficiaries whose disabilities may prevent them from reading the standard materials. The proposed translation and cultural competency requirements form part of a larger goal of advancing health equity as it applies to Medicare Advantage, Part D and D-SNPs.		
- D-SNP sponsors must provide materials to enrollees on a standing basis in any non-English language (that is the primary language of at least 5 percent of the individuals in a plan benefit package service area) or accessible format (using auxiliary aids and services) upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format. - Provider directories must list providers' cultural and linguistic capabilities (including ASL proficiency). - CMS will require fully integrated dual eligible special needs plans ("FIDE SNPs"), highly integrated dual eligible special needs plans ("HIDE SNPs"), and applicable integrated plans ("AIPs") to follow the same translation requirements as MA	- D-SNP sponsors will need to evaluate which languages to which their materials must be translated and translate the materials into those languages. - D-SNP sponsors will need to implement a translation-by-request system for languages spoken by under 5 percent of individuals in a service area. - D-SNP sponsors will need to update provider directories to	- Whether the translation requirements as applied to D-SNPs adequately address beneficiaries' translation needs. - The extent of the logistical burden incurred when translating D-SNP materials into all required languages.

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plans, as well as any additional languages required by the Medicaid translation standard. - CMS will require MAOs to ensure that services are provided in a culturally competent manner to individuals (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minorities; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality	include cultural and linguistic capabilities. - D-SNP sponsors will need to update policies to reflect the expanded requirements for culturally competent care.	
Advancing Equity in Telehealth Access § 422.112		
CMS Concern: CMS intends to address disparities in telehealth access due in part to low digital health literacy, especially among populations who already experience health disparities. The effect of digital health literacy on healthcare access can be especially pronounced in the Medicare context, with many enrollees being 65 or older. In addition, those already adversely affected by poverty and inequality are more likely to experience challenges due to digital health literacy. The increase in use of telehealth services during the COVID-19 pandemic exacerbated this problem, with more providers and beneficiaries relying on telehealth to safely meet their healthcare needs.		
Purpose: The purpose of the proposed telehealth require is to ensure that all beneficiaries can utilize telehealth resources. CMS is giving plans significant flexibility in both the content of their telehealth education programs and the manner by which they identify those with low digital health literacy. CMS's justification for its flexibility is the novel nature of telehealth education programs in Medicare Managed Care. CMS expects plans to use a variety of content and methods to identify and educate those with lower digital health literacy, with the eventual goal of discovering best practices.		
- MAOs will be required to implement procedures to identify enrollees with low digital health literacy and offer them digital health education. CMS deliberately does not provide specifics governing the manner by which MA plans implement digital	- MAOs should develop procedures to identify enrollees with low digital health literacy.	- The extent to which the requirement to identify beneficiaries with low digital health literacy places a

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health literacy programs. This flexibility is intended to allow MAOs to determine best practices for this novel program.	- MAOs should compose educational materials that teach digital health literacy.	financial and logistical burden on MAOs - The extent to which the obligation that MAOs provide data on their digital health literacy programs places a financial and logistical burden on MAOs
Incorporating a Health Equity Index ("HEI") into Star Ratings §§ 422.162, 422.164, 422.166, 422.260, 423.184, 423.186		
CMS Concern: Through the HEI reward system, CMS is addressing disparities in health care for those with social risk factors. To that end, CMS intends to encourage plans to focus on improving care for beneficiaries with social risk factors.		
Purpose: CMS's purpose in implementing the HEI to is incentivize MA, cost plan, and Part D sponsors to encourage high quality care among beneficiaries with SRFs. This is part of the broader CMS goal of advancing equity. The HEI system is designed to reduce disparities in care. This is framed as an issue of fairness to both plans and enrollees, as adjustments to Star Ratings would avoid penalizing plans for including enrollees' social risk factors, while also rewarding quality care for enrollees with social risk factors. The prevalence of many social risk factors vary based on a plan's location. This change would avoid the Star Ratings system punishing plans based on which social risk factors are common or uncommon in their locations.		
- CMS will establish an Health Equity Index (HEI) reward, which will reward plans that provide high-quality care to individuals with Social Risk Factors (SRFs). The HEI reward will also reduce the weight of patient experience/complaints in Star Ratings. - CMS will modify its current hold harmless policy for Health Plan Quality Improvement and Drug Plan Quality Improvement measures, which currently excludes improvement measures from the Star Ratings calculation for 4-star and higher plans if its inclusion could negatively impact the overall rating. Under	- MAOs should update their policies and procedures related to health care for beneficiaries with social risk factors -MAOs should identify plan locations where beneficiaries are more likely to be affected by social risk factors and adjust strategies to better ensure high quality care as it related to those social risk factors.	- Potential additional ways to identify enrollees who have a disability that could be incorporated over time and whether the same process and standards should be used for the CAI adjustment as well - How CMS could include enrollees who develop a disability after aging into the Medicare program

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the new hold harmless policy, the improvement measures can only be excluded for plans with 5-star ratings. - CMS will add a rule for the subregulatory removal of certain Star Ratings measures when a measure steward other than CMS retires the measure, meaning that plans will not be evaluated based on obsolete measures. - CMS will remove the 60 percent rule, which excludes from Star Ratings contracts with 60 percent or more of their enrollees in Federal Emergency Management Agency (FEMA) designated Individual Assistance areas at the time of an extreme and uncontrollable circumstance. Due to the COVID-19 pandemic, CMS temporarily suspended the 60 percent rule. This provision of the Proposed Rule would permanently replace the 60 percent rule. Instead, CMS will exclude from Star Ratings any measures it identifies as extreme outliers.		

[i] We have summarized and, in some cases, paraphrased the language of the Proposed Rules. Please refer to the actual text of the Proposed Rule for precise language.