TRIPLE-S ADVANTAGE

January 16th, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

VIA ELECTRONIC SUBMISSION
http://www.regulations.gov

Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Honorable Administrator Verma:

Triple-S Advantage, Inc. (Triple-S Advantage) appreciates this opportunity to comment on the proposed rule referenced above with an intended effective date scheduled for calendar year 2019. As a way of background, Triple-S Management Corporation (Triple-S) is an independent licensee of the Blue Cross Blue Shield Association. Triple-S has been providing insurance coverage to the people of Puerto Rico for more than 55 years. As part of the health insurance lines of business, Triple-S has provided high quality health insurance to one of every three Puerto Rico residents and currently serves one of every five members of the island's Medicare Advantage program through its subsidiary and Medicare Advantage Organization (MAO), Triple-S Advantage.

Triple-S Advantage, as part of the Puerto Rican healthcare community, acknowledges and appreciates the attention and efforts that the Centers for Medicare and Medicaid Services (CMS) has devoted to the island's health care challenges in past years. However, Puerto Rico continues to face increasing disparity in both Medicare Fee-For-Service (FFS) and Medicare Advantage (MA) funding, much of which has been a direct impact of reductions imposed by the Patient Protection and Affordable Care Act (ACA). Confident that a permanent resolution of these continuing challenges is viable, Triple-S welcomes the opportunity to serve as a resource to CMS as the administration moves to finalize each proposed rule. We look forward to working with you to bring stability to a program that is vital to the health and well-being of so many American citizens residing in Puerto Rico.

Given the devastation caused by Hurricane Maria and its impact on our health care delivery system, it is particularly important that policy decisions made by CMS reflect an understanding of the enormous obstacles Puerto Rico residents face every day. Damage to infrastructure and lack of electricity continue to be a major challenge. As we consider policies set forth by CMS, our perspective is shaped by our new post-hurricane reality.

In general, Triple-S Advantage is supportive of a majority of the proposals CMS set forth in the draft rule. In our opinion, these proposals are intended to implement efficiencies for the overall administration of Medicare benefits for which plans and providers are accountable. Nonetheless, Triple-S Advantage respectfully encourages CMS to finalize evaluation and issuance of final rules after considering, wherever possible, additional flexibilities and comments received from stakeholders. In particular, we would like to bring to your attention the comments detailed in Appendix I to this letter.

In addition to our comments on the important issues CMS has raised, we would like to remind you that Puerto Rico has longstanding policy priorities we would like to see addressed throughout this year's regulatory cycle. Those priorities include the use of a proxy in establishing Medicare Advantage benchmarking formulae, addressing our Medicaid cliff, and providing Puerto Rico beneficiaries access to the Medicare Low-Income Subsidy program.

Thank you very much for your consideration of our comments. We would welcome the opportunity to serve as a resource as you further consider policies affecting health care delivery in Puerto Rico. If we can be of assistance, please contact Carlos Rodriguez Ramos, Vice President of Legal Affairs and Chief Legal Counsel at Triple-S. He can be reached at crodrig@ssspr.com or 787-281-2315.

Sincerely,

Madeline Hernández-Urquiza
President
Triple-S Salud & Triple-S Advantage

Appendix I

MEDICARE PROGRAM; CONTRACT YEAR 2019 POLICY AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE, MEDICARE COST PLAN, MEDICARE FEE-FOR-SERVICE, THE MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS, AND THE PACE PROGRAM (CMS-4182-P)	
PART D: PROPOSALS BY CMS	
SUMMARY OF CMS' PROPOSAL	**COMMENTS BY TRIPLE-S ADVANTAGE**
Effective CY2019 and pursuant to the CARA Act, CMS proposes to institute the use of voluntary drug management programs to monitor potential overutilization of "frequently abused drugs" and placing system edits in the form of prescriber verification and point of sale lock-ins. The proposal recommends using criteria for identifying "potential at risk beneficiaries" and overseeing utilization by adopting case management protocols similar to the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS).	Triple-S Advantage is in agreement with CMS' proposal to implement use of drug management programs and commends the Administration for considering moving in this direction. Although in Agreement, Triple-S Advantage would request CMS' consideration to delay implementation of this proposal in order to allow MAO's sufficient time to implement required operational changes and assess additional administrative costs which will require additional analysis as we draw near bid submission deadlines or 2019.
CMS proposes defined terms for the following: Potential At-risk beneficiary, At-risk beneficiary, frequently abused drug, clinical guidelines, program size, exempted beneficiary (§423.100)	In its review of CMS' proposal, Triple-S Advantage understands that the definition of frequently used drugs should be broadened to include other controlled substances such as benzodiazepines, sedatives and muscle relaxants. In addition, we note that the proposed clinical guidelines for CY2019 in summary are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. If upon Prescriber verification, an enrollee's prescriber provides information indicating the need for obtaining frequently abused drugs from more than one prescriber and/or more than one pharmacy, isn't this information relevant in determining the appropriateness of the prescribed medications?

	If so, why would an enrollee in such circumstances be considered an "At risk" beneficiary? Triple-S Advantage would be interested in further clarification of this proposal. Also Triple-S Advantage would request more clarity in the applicability of the proposal in regards to the term group practice prescribers which is not common on the island.
Preclusion List Requirements for Prescribers in Part D and Providers and Suppliers in Medicare Advantage, Cost Plans and PACE	CMS proposes eliminating the prescriber and provider enrollment requirement and compiling a "Preclusion List" of individuals and entities that fall within either of the following categories: (a) are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Under this option, CMS would make the Preclusion List available to Part D prescription drug plans and Medicare Advantage plans. Plans would then be required to deny claims from or written by prescribers and providers on the list. Triple-S concurs with the distribution of a Preclusion List as suggested by CMS. Nonetheless, Triple-S feels that further clarification is warranted pertaining to the timeliness of publication and update of the list for all MAO's. Additionally, Triple-S feels that the distribution of said list should include basic hold harmless and indemnification language in favor of the MAOs.

Proposal to Reduce the Burden on Plans by Eliminating MA Plan Notice of Forwarded Appeals.	CMS also is proposing to remove the current requirement that MA plans send notice to an appellant when his/her appeal case file is forwarded to Medicare's Part C IRE. Under its contract with CMS, the Part C IRE will continue to notify MA enrollees of forwarded cases. Triple-S concurs with eliminating this redundant enrollee notice as it would ease burden on plans without adversely impacting enrollee protections. Additionally, CMS should also consider requesting from the IRE the use of electronic notifications to enrollees.
Default Enrollment & Seamless Conversion Enrollment	CMS is proposing to codify the current optional enrollment mechanism that allows MA organizations to provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA-eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare with significant limitations. In addition to other limits, CMS' proposal would limit default enrollments of this type to individuals remaining in a Medicaid managed care plan offered by the same parent organization offering the MA plan. Triple-S commends CMS in proposing enrollment processes, that could streamline the selection of an MA plan upon initial eligibility. As such, Triple-S recommends that the proposed enrollment process be treated as an opt-out process, which will facilitate seamless conversion and reduce member disruption and confusion.
Proposal to limit access to frequently abused drugs to pharmacies and prescribers selected according to the beneficiaries' preference (§423.153(f)(9-13)	Triple S is in agreement with this proposal. CMS should also consider extending this initiative to Dual Eligible beneficiaries, and not limited solely to LIS. Medicare beneficiaries residing in US Territories such as Puerto Rico, are not eligible by statute to LIS. Since we believe this initiative is aligned to CMS efforts driving efficient managed care and reducing fraud, waste

	and abuse of the Medicare Program, it should be open to all dual eligibles.
CMS PROPOSALS FOR MEDICARE ADVANTAGE	
SUMMARY	**COMMENTS BY TRIPLE-S ADVANTAGE**
PROPOSAL TO INCLUDE REGULATION ALLOWING ADDITIONAL FLEXIBILITIES IN MA UNIFORMITY REQUIREMENTS	
CMS proposes to consider more flexibility in MA Bid uniformity requirements while upholding non-discrimination requirements with the purpose of increasing availability of coverage options for the most vulnerable populations by allowing: a) reduced cost sharing for certain covered benefits, b) tailored supplemental benefits, c) lower deductibles for enrollees with specific medical criteria §422.100(d)	Triple-S Advantage commends CMS' for its initiative to allow more flexibility for bid submission requirements. Nonetheless, as an MAO operating in Puerto Rico, we continue to be subject to disparities that impact rate setting methodology for MA Plans in Puerto Rico. Until a permanent solution is identified, we continue in a disadvantaged position in terms of the availability to tailor plan offerings to accommodate the needs of the most vulnerable populations with higher utilization costs.
PROPOSAL TO ADOPT PART D TIERING EXCEPTIONS	
Part D Tiering Exceptions	Triple-S Advantage is interested in further clarification regarding this proposal. For purposes of reviewing CMS proposal for Part D Tier Exceptions specifically for Mixed tiers, CMS limits the definition of an alternative drug specifically to a preferred or formulary drug used "for a treatment of the same condition". Triple-S Advantage would appreciate clarification of the meaning of the term "type" as stated in § 423.578(a)(6)(i) and (ii). If we would consider, for example, alternatives to treat Diabetes, our formularies include drugs from different categories such as: SGLT2 inhibitor, DPPIV inhibitor, Biguanides, etc. In its proposal, we do not see that CMS distinguishes conditions among categories and their mechanism of action. The prescriber has to justify that the agent within the condition has not been effective in treating the condition, not the drugs with the same mechanism of action in the category. In that circumstance, the

	biguanide could be an alternative to an SGLT2 inhibitor. However, if seen from the perspective of mechanism of action, then the biguanides would not be an alternative to the SGLT2 inhibitor. We believe the evaluation should be based on the same mechanism of action. For example: An alternative for a SGLT2 inhibitor on tier 3 should be another SGLT2 inhibitor of a lower tier. If there is no other SGLT2 inhibitor on a lower tier, the tier exception would be denied. In addition, to ensure appropriate enrollee access to tiering exceptions, we are proposing to revise § 423.578(a)(6) to specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Under this proposal, however, plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs. Please clarify. Examples would be helpful to further understand CMS' proposals regarding Tier Exceptions. We suggest that CMS more specifically define what an alternative drug is. For example, a member may request a tiering exception for Captopril (Tier 4) and Plan Sponsor has Lisinopril (Tier 2) and Irbesartan (Tier 1). What is the appropriate cost sharing tier? All drugs are for hypertension but have different mechanisms of action. Captorpil and Lisinopril are ACE inhibitors (have same mechanism of action) whereby Irbesartan is an ARB. Should tiering exception be approved for

	Tier 2 or Tier 1? Tier 1 could technically be considered the lowest applicable alternative. Additional guidance from CMS is needed.
PROPOSED POLICY CHANGES FOR PART D TRANSITION SUPPLIES	
CMS proposes to make two changes to regulations governing Part D Transition supplies summarized as follows: 1. Shorten the required transition days' supply in the LTC setting to the same supply currently required in the outpatient setting 2. A technical change to the current required days' transition supply in the outpatient setting from "30 days" to a month's supply (this is in response to inquiries from plan sponsors regarding scenarios involving medications that do not easily add up to a 30 days' supply when dispensed – e.g. drugs that are typically dispensed in 28-day packages)	Triple-S Advantage has evaluated through its Pharmacy Benefit Manager the impact of CMS' proposals. In summary, we suggest that CMS define the meaning of "minimum days' supply" that would qualify as a month's supply. Although we recognize a 28 day fill would be a month's supply under the guidance, would a 21 day supply be also considered as a month's supply? Or is CMS just saying that a month's supply will be based on the number submitted by Plan Sponsor on the PBP? The current language seems confusing given it says that the month's supply will be what was submitted in the PBP or what the prescriber submits, whichever is less. Therefore, under the following scenario, how would the proposal play out? Plan Sponsor has a PBP plan benefit of 30 days. In the transition window, a claim for Insulin for (Humulin 2 vials for 17 DS) is approved as a transition fill. Would a second claim for Humulin within the 90 day transition window process as paid? Under current guidance, it would need to pay given you need to allow up to a 30 days' supply and the prior fill was less than a 30 day supply. We would be interested in CMS providing further examples to better understand the proposal and be in a position to provide additional comments.
CMS' REQUEST FOR INFORMATION ON POINT OF SALE DISCOUNTS	
CMS is soliciting comment from stakeholders on how to most effectively design a policy requiring Part D Sponsors to pass through at the Point of Sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construction on costs to both beneficiaries and Medicare, competition, and efficiency under Part D. CMS puts forth for consideration potential parameters for such a policy and seeks detailed comments on the	We believe the minimum rebate percentage shared at the point of sale should be no less than 30% and no more than 75% to achieve the balance of outcomes identified by CMS. It is important that the POS rebate be high enough to impact beneficiary's behavior, where appropriate. It is also important that it not be so high so that the cases where there is negative DIR are minimal. We believe that having more rebates passed through at the point of sale so that

merits, as well as the merits of any alternatives that might better serve the goal of reducing beneficiary costs and better aligning incentives for Part D Sponsors with the interests of beneficiaries and taxpayers. CMS specifically seeks comment on how this issue could be addressed without increasing government costs and without reducing manufacturer payments under the coverage gap discount program.	members can pay closer to the actual cost of the drugs they are using and so there is more transparency around rebates, will lead to higher competition between drug manufacturers, fewer rebates bundles and ultimately higher rebates. In summary, this requirement would be pro-competitive for PBMs, manufacturers, and plan sponsors, in our view. If instituted, it's strongly recommended that pharmaceutical manufacturers agree to pay prospective rebate estimate payments so there is no financial risk to Plan Sponsors and PBMs. If one objective of this change is for pricing to be reported consistently, shouldn't CMS require a specific percentage of rebates to be passed through at the point of sale? Otherwise, there could still be situations in which some plan sponsors choose to report more of the rebates at the point of sale (e.g. to show lower copays in the plan finder) while others report less rebates, in order to reduce premiums? Additionally, PBMs could set up the DIR reporting approach such that a higher % of rebates are reported in therapeutic categories in which profitability is higher, and a lower % of rebates are reported in therapeutic categories in which profitability is lower, to drive plan selection by the most desirable patients. Below are comments to subparts within this proposal: Manufacturer Rebates to the Point of Sale: The proposed change impacts not only DIR, but potentially drug pricing (to apply POS rebates) and MPF. The most significant burden in the methodology outlined in the proposed rule will be borne by plan sponsors/PBMs due to the complex system changes that will be needed to comply with the periodic estimation and re-estimation of the rebates as well as the associated reporting, reconciliation and compliance burden. CMS must provide ample time for plans/PBMs to develop the systems,

	processes, and business arrangements that support such a policy (no less than 12-18 months). DIR Rebates as CMS outlines are a source of plan profits. For markets with low funding/low profits such as Puerto Rico, this impact could be significant to a plan's finances of not somehow counteracted. The suggested methodology is very complex. Plan finder, while useful to members and their representatives while shopping, is not always part of the sales and marketing process around Part D benefits. Given that there is significant variability in rebates from class to class, members may have a difficult time understanding what cost sharing they will be expected to pay for a drug and may not understand that premiums are rising because of this new benefit. CMS should revise its education and model marketing materials to contemplate this new paradigm. Specified Minimum Percentage: If this program is not implemented with the appropriate safeguards, this could place plan sponsors at significant financial risk. The risk of unpaid rebates could be a significant problem. We believe the minimum rebate percentage shared at the point of sale should be no less than 30% and no more than 75% to achieve the balance of outcomes identified by CMS. It is important that the POS rebate be high enough to impact beneficiary's behavior, where appropriate. It is also important that it not be so high so that the cases where there is negative DIR are minimal. We believe that having more rebates passed through at the point of sale so that members can pay closer to the actual cost of the drugs they are using and so there is more transparency around rebates, will lead to higher competition between drug manufacturers, fewer rebates bundles and ultimately higher rebates. In summary, this requirement would be pro-competitive for PBMs, manufacturers, and plan sponsors, in our view. If instituted, it's strongly recommended

	that pharmaceutical manufacturers agree to pay prospective rebate estimate payments so there is no financial risk to Plan Sponsors and PBMs. If one objective of this change is for pricing to be reported consistently, shouldn't CMS require a specific percentage of rebates to be passed through at the point of sale? Otherwise, there could still be situations in which some plan sponsors choose to report more of the rebates at the point of sale (e.g. to show lower copays in the plan finder) while others report less rebates, in order to reduce premiums? Additionally, PBMs could set up the DIR reporting approach such that a higher % of rebates are reported in therapeutic categories in which profitability is higher, and a lower % of rebates are reported in therapeutic categories in which profitability is lower, to drive plan selection by the most desirable patients. Applicable Average Rebate Amount: Rebate Year: It will be a burden to have the need to calculate the average rebate amount at the beginning of the year. Early in the year, how is a PBM able to calculate the average rebate amount? For a PBM, estimating rebate eligibility at a claim level takes time – the formulary set-up, number of competitors covered, market share of the contracted product, patient cost-share, and PAs could all impact rebate eligibility. Would be challenging to do this "real time" at the beginning of the year. Rebate eligibility will be unclear until manufacturers make payment decisions on Q1 utilization after the close of the quarter. Although this could be the most accurate estimate for POS rebates, it is difficult to anticipate rebates to be received. Many factors, such as market share, etc. impact rebates amounts. The amounts to include as POS rebates may be based on prior year and adjusted for new contracts, in the same way amounts are estimated for example for budget purposes.

	Plan-Level Average: This could have an impact on timing of CMS bid submissions because of the significant effort plans sponsors will require to work with PBM and actuaries to develop new bidding method. Currently, rebates billed data may be provided at the PBP level. For PDE there already are fields to report POS rebates, but these are not required fields. We agree that it is most appropriate to calculate average rebates at a plan level, even though it creates an additional burden for plan sponsors and their PBMs, and could be inaccurate for lower membership plans that have high volatility in the utilization profile. This idea makes sense because each plan could have a different formulary and benefit design, which could alter the rebate amount paid by drug. Based on the above, we recommend a very clear methodology to derive these calculations if implemented. Drug Category or Class: This could place some plan sponsors with lower membership to potentially be less competitive because they do not generate aggressive rebates. CMS points out two main issues with this approach – the consistency of the classification system and the classes where there is only one rebated drug. The former can be resolved by ensuring CMS develop a uniform classification system that is maintained and published by CMS and that is crosswalked to RxCUI/GPI/GCN. The latter can be addressed by combining classes where it is likely that there is only one drug. However, another issue that has not been addressed is what happens when one plan has rebates for more than one drug in the class and another only has one. Will CMS use the lowest common denominator in its classification system? We believe that sponsors and manufacturers will often be able to reengineer their competitors' pricing positions but we DO NOT believe this will be as anti-competitive as CMS has been led to believe given the yearly competitive process

	that all parties engage in during formulary/bid season and the timing offsets, changing list prices and variation in pharmacy pricing during these periods. Category definition is important, because being too broad could result in very inaccurate rebate estimates, while, being too specific could result in disclosure into a particular plan sponsor's rebate arrangements that are confidential information and should not be available to other Plan Sponsors/PBMs. For example, insulin rebates vary significantly from DPP-4 rebates. Including all of diabetes as a "drug category" would mask the individual rebates for DPP-4s vs. Insulins, but would put a plan sponsor at risk – e.g., reported rebates at the point of sale might vary significantly from actual rebates, if utilization for either DPP-4s or Insulins changed from current levels. Meanwhile, if only DPP-4s were included in a drug category, a plan sponsor covering only one DPP-4 would be revealing their proprietary rebate arrangements. Any drugs that are the only rebated drug in their class could be grouped in a "Miscellaneous" bucket, for which average rebates could be calculated. The risk here is that this may be a large umbrella, and utilization changes within this umbrella could significantly shift average rebates, resulting in inaccurate POS estimates. Weighting: We believe weighting should be done on a quarterly basis because the period is long enough to capture variation and only require 4 updates per year, and at the same time is frequent enough to be consistent with a common rebate billing interval, during which there can be changes in pricing or other rebate terms. Rebates must be reported based on average expected rebates for the current year, not only historical experience – how can a PBM know what to expect for the current year? Rebates could fluctuate significantly within a given year – e.g. Hepatitis rebates likely looked very different before vs. after the release of

	Harvoni. Likewise, PBMs may anticipate high rebates in Hepatitis C based on historically high rebates, only to find in 2018 that the growing share of lower-net-cost (and lower rebate) Mavyret grows significantly, materially reducing rebates in the category. Timing: Standard is for rebates to be billed quarterly. Utilization changes constantly (which could change the average) but rebate eligibility is typically billed quarterly. Thus, quarterly is likely most frequent timing that would make sense. Point-of-Sale Rebate Drugs: CMS may consider piloting this program for one year with high rebate classes such as insulin or hepatitis C before expanding it to all classes. Long term if it works for some classes, it should work for all. Point-of-Sale Rebate Example: May change rebate strategies. This methodology will likely result in lower-rebate drugs benefiting from higher rebates offered by competitor products. Thus, there may be an incentive here for newer competitors to price their drugs at a lower WAC, and then to offer very low rebates. And there also may be an incentive for PBMs not to accept the lower rebates, to avoid having to apply a competitor's rebates to this newer, less-discounted product. To illustrate the issues with this approach, let's assume that drug A from this example had a rebate of 70%, drug B from this example had a rebate of 40%, and drug C from this example had a rebate of 5%. Therefore, the net cost of drugs A and B would be $60, while the net cost of drug C would be $71.25. The average rebate, applied to all drugs in the class, would be 59%. Therefore, the drug costs would appear in the plan finder tool to be $141.12 for drug A, $70.56 for drug B, and $52.92 for drug C. This plan might disproportionately drive share to drug C, which is actually the most expensive drug (in terms of net cost) in the

	category. Had this payer not contracted drug C, costs would instead appear to be $138.20 for drug A, $69.10 for drug B, and $75.0 for drug C. Not contracting drug C would provide a more accurate idea of costs and drive utilization to the lowest-cost drug, and might therefore be the best approach for this plan. Additional Considerations: PDE calculation logic will need to consider the POS rebates field. As of now it is not a required field for reporting PDE. This policy could have a different impact on the Medicare Platino Dual Eligible SNP plans in Puerto Rico given that the LIS/LICS offset does not apply in the same way. CMS should work with the affected plans to understand the implications of this change before finalizing the policy, and may consider excluding these plans from the requirement.
MIDYEAR FORMULARY CHANGES	
CMS is soliciting comment as to whether CMS should consider immediate substitution, potentially in limited circumstances, of specified generics for which Part D sponsors could have previously requested formulary approval.	We understand there may be scenarios in which although a generic has already entered the market, the generic drug price is still similar to or equal to the brand drug. If the brand drug is still receiving rebate dollars, the total net cost of the brand would be less for Plan Sponsor, member and the Medicare Part D program. It may take a couple of months until a newly approved generic costs less to the Part D program than the brand. Plan Sponsors should have the flexibility to make generic substitutions not immediately after generic market entrance but when the conditions are at least as favorable as the branded product (from a cost perspective). There may also be scenarios in which the generic is available in the "market" but not in some jurisdictions such as US Territories. This is also a point that should be considered by CMS in determining the flexibility to be afforded for generic substitution.

PRECLUSION LIST REQUIREMENTS FOR PRESCRIBERS IN PART D AND PROVIDERS AND SUPPLIERS IN MEDICARE ADVANTAGE, COST PLANS AND PACE)	
CMS proposes to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim drug prescribed by a physician or eligible professional to be covered.	Triple S is in agreement with this approach. This approach would reduce prescriber burden, while providing a safeguard to reduce risks. Although in Agreement, Triple-S Advantage would request that CMS clarify the following: Will the Claim processing date (as opposed to date of service) be used by CMS to apply the provisional coverage rule? For example, what would happen if a drug is dispensed to a beneficiary (date of service) prior to his prescriber's inclusion in the preclusion list but the pharmacy processes the claim after the date of inclusion? Will the 90-day provisional coverage begin on the date of service or on the date the claim is processed by the pharmacy? We recommend that the Claim processing date is used by CMS to apply the provisional coverage requirement. 2. Will a prescriber be precluded immediately after it is included in the preclusion list or is CMS considering to allow different dates of preclusion effectiveness on a case by case basis? 3. Regarding provisional coverage, we need to confirm with CMS whether our understanding of this rule is correct. As proposed, we understand that once the 90-day provisional coverage period begins, the beneficiary will be able to fill any and all prescriptions from the precluded prescriber during such 90-day period. For example, will the member be able to take multiple fills during the 90-day provisional coverage period? (E.g. first a 30 day fill, then another 30 day fill, and then a 90 day fill). Finally, under the previous and the proposed rule, plan sponsors are required to send written notice to the beneficiary of the prescriber's presence on the preclusion list. We believe CMS can complement this requirement by allowing beneficiaries to be more informed about the preclusion status of their prescribers. For example, the preclusion list

	could be posted for easy member access so they know at a moment in time which prescribers are precluded.
PART D E-PRESCRIBING STANDARDS	
Updating the Part D E-Prescribing Standards	PBM handles medication history transactions, which currently use the NCPDP SCRIPT 10.6 standard. CMS is also proposing to adopt NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for the medication history transaction. In that regard, the proposed implementation date (January 1, 2019) seems aggressive given that it will take some time for the affected entities to update their systems. For example, if CMS implements this change, Suprescripts will first need to update its systems and then PBM will update theirs. The next step is to go through a certification process with Surescripts and, afterwards, updates will go into production upon passing the certification process. Our recommendation would be for CMS to implement a transition process where either both versions (NCPDP SCRIPT 10.6 and 2017071) were allowed to be used by PBMs.
PROPOSAL TO ELIMINATE THE COMPLIANCE TRAINING REQUIREMENT FOR FDR'S	
CMS' proposal is to reduce the burden of the Compliance Program Training Requirements for FDRs	Triple S is in agreement with the elimination of this requirement for FDRS. As established in the proposed ruling, this change will allow sponsoring organizations, and FDRs the maximum flexibility in developing and meeting training requirements associated with effective compliance programs.
PROPOSED POLICY CHANGES FOR REVISION TO TIMING AND METHOD OF DISCLOSURE REQUIREMENTS	

CMS' proposal is to allow the electronic delivery of certain information usually provided in hard copy such as the Evidence of Coverage, also to modify the timeframe for the delivery of the EOC, in order to deliver it the first day of the annual election period rather than 15 days prior to the AEP.	Triple S is in agreement with the proposal. We strongly believe this initiative reduces the margin of error in complex documents due to the limitation of time associated with the production, revision, printing and mailing. Also, Triple-S Advantage agrees with CMS' assumption that this initiative will help beneficiaries to focus on ANOCs for a well informed decision making process.
CHANGES TO RULES GOVERNING PLAN COMMUNICATIONS: DISCLOSURES AND MARKETING/ENROLLMENT	
CMS is proposing to modify annual enrollment disclosure requirements as follows: 1) Require MA plans and Part D sponsors to provide information by the first day of the annual enrollment period, rather than 15 days before, and 2) Allow plans to meet their disclosure requirements by posting the explanation of coverage, summary of benefits, and provider network information on their website instead of mailing hard copies to beneficiaries, subject to the delivery of hard copies upon request. With the Proposed Rule, CMS is inclined to narrow the definition of marketing materials, which are those required to be submitted for approval subject to 45 day turnaround timeframes (some 10 day exceptions), to only those that influence enrollment decision making. In addition, CMS is proposing to add language in regulations that would disallow marketing during the proposed new open enrollment period (Cures Act OEP- proposed to be from January 1 through March 31 each year) to certain audiences who have already chosen coverage whether by default, seamless or opt in option of enrollment.	Triple-S Advantage commends CMS' in its efforts to reduce the administrative burden, costs and environmental hazards created by mandatory use of printed materials. Digitalization of materials and additional flexibilities in submission for review and approval of certain materials increases efficiencies in terms of distribution and outreach to Members while also guaranteeing access to hard copies for those who require printed materials. Triple-S Advantage is in agreement with the proposal since materials that are not considered marketing would fall under less stringent communication requirements. Nonetheless, to be in a position to responsibly issue comments to the proposed course of action, we would need additional guidance in terms of how CMS will manage regulatory oversight of this proposal. In terms of limiting marketing activities during OEP, Triple-S Advantage would rely on additional guidance from CMS on how to implement reasonable measures that would position the organization as compliant with the proposal. Further clarification on behalf of CMS would be welcome.